



AMA
African Medicines
Agency

Expression of Interest - Request for Proposal

Digital Platform for Continental Medicines Regulation

17 August 2026

Issued by: African Medicines Agency (AMA) through Garnet Partners Ltd

Administered by Garnet Partners Ltd as Contract Management Partner and Fiscal Administrator

CONFIDENTIAL

Letter of Invitation

17 August 2026

Dear Sir / Madam,

RE: EXPRESSION OF INTEREST - REQUEST FOR PROPOSAL FOR THE DIGITAL PLATFORM FOR CONTINENTAL MEDICINES REGULATION

The African Medicines Agency (AMA), a specialized agency of the African Union mandated to coordinate and strengthen the regulation of medicines and health products across the continent, is establishing a digital platform to support continental medicines regulation. This work is administered by Garnet Partners Ltd as Contract Management Partner and Fiscal Administrator.

Acting on behalf of AMA, Garnet Partners Ltd invites qualified and eligible firms to submit proposals for the design, build, integration and delivery of the platform, organized into five components as set out in this RFP:

- Component 1 - eCTD v4.0
- Component 2 - Data Foundations and Integrations
- Component 3 - Enterprise Setup
- Component 4 - Systems Integration
- Component 5 - Portal and RIMS (optional scope)

Vendors may bid for one or more components, individually or as consortia / prime-sub teams, as described in Chapter 3.

This RFP comprises the following:

- This Letter of Invitation
- Data Sheet
- Chapter 1 - AMA Context
- Chapter 2 - AMA Digital Strategy Overview
- Chapter 3 - Selection Process and Key Dates
- Chapter 4 - Selection Approach, Criteria and Minimum Requirements
- Chapter 5 - Solution Scope and Requirements
- Chapter 6 - Response Format and Vendor Questions
- Appendices A to E

Firms will be selected using the weighted evaluation approach described in Chapter 4, subject to a responsiveness check (Section 4.1) and mandatory minimum qualifications (Section 4.2). AMA is not bound to accept any proposals.

Interested firms shall submit an Expression of Interest (EOI) no later than 26 August 2026 for preliminary engagement. Complete Technical and Financial Proposals shall be submitted in English no later than 17:00 hrs (CAT) on Friday, 18 September 2026, by email to Garnet.Tenders@garnetpartners.rw with a copy to AMATender@au-ama.africa. Late submissions shall not be accepted under any circumstances. Proposals shall remain valid for a minimum period of ninety (90) days from the submission deadline, and all prices shall be quoted in United States Dollars (USD).

Requests for clarification may be submitted in writing to the addresses above, in accordance with Section 3.4 (questions due 26 August 2026; consolidated responses published 31 August 2026).

Bidders shall include the following mandatory documents with their Technical Proposal:

- Certified copy of Certificate of Incorporation (company registration).
- At least two (2) contactable reference projects of comparable scope (see Section 4.2).
- CVs of proposed key personnel, with certified / notarized copies of academic qualifications and professional certifications.
- Signed statements of availability for the proposed experts.
- Duly signed Bid Submission Forms, with names of authorized representatives (Power of Attorney).

- Tax compliance certificate.
- Proof of professional indemnity and cyber-liability insurance.
- Signed statement of no conflict of interest and no history of debarment.
- Audited accounts or equivalent financial disclosure for the most recent two fiscal years (see Section 4.2).
- For consortia / joint ventures: a Joint Venture / Association Agreement naming the lead firm.

We look forward to receiving your expression of interest and subsequent proposals.

Yours sincerely,


Felicien Muvunyi
Managing Partner, Garnet Partners Ltd
(for and on behalf of the African Medicines Agency)



Executive Summary

Purpose and issuer. The African Medicines Agency (AMA), a specialized agency of the African Union, is procuring a Digital Platform for Continental Medicines Regulation. AMA is the contracting authority and retains responsibility for all procurement decisions, while Garnet Partners Ltd serves as Contract Management Partner, Fiscal Administrator and administers the procurement process on AMA's behalf. The procurement is being conducted as a combined Expression of Interest and Request for Proposal: intent to respond is due 26 August 2026, and full technical and financial proposals are due by 17:00 CAT on Friday 18 September 2026. Proposals shall be quoted in USD and remain valid for ninety days. The immediate business driver is AMA's continental listing exercise, which expected to begin receiving of dossiers in January 2027 and requires the core digital capabilities needed to support dossier submission, intake, and review to be operational by that time.

What is being procured: AMA is procuring a single, integrated and layered platform, rather than a collection of standalone systems. For procurement and delivery purposes, the scope is organized into five components. Vendors may bid for one or more, individually, as consortia or as prime/sub teams:

- (1) eCTD v4.0 — dossier intake, validation, lifecycle and document management;
- (2) Data Foundations — the AMA-SPOR master-data layer, built to ISO IDMP and exposed via HL7 FHIR R5, together with data governance, data quality and the reusable data products that make regulatory data consistent and shareable across the platform;
- (3) Enterprise Setup — identity and access, cloud hosting, cybersecurity controls, backup and recovery and audit logging;
- (4) Systems Integration — the Systems Integrator acting as the prime delivery partner, responsible forend-to-end solution integration, cross-vendor coordination and integration governance;
- (5) Portal and RIMS — the sponsor gateway, AMA internal portal and configurable regulatory workflow and information management capabilities.

A phased system, with a staged award. Delivery is deliberately phased and the commitment is staged. This RFP seeks proposals and pricing for both Phase 1 and Phase 2. The resulting contract is expected to cover both phases; however, AMA's commitment and contract award is limited to Phase 1. Commencement of Phase 2 is subject to successful completion of the MVP Stage-Gate and AMA's written Authorization to Proceed. AMA is under no obligation to proceed with Phase 2. The requirements also include requirements for later phases or vendor awareness and planning.

- **Phase 1 — MVP (early 2027).** Will deliver a deliberately lean MVP focused on the capabilities required to support AMA's initial continental listing activities. It will include the sponsor gateway; secure eCTD (ICH M8 / v4.0) intake, validation and document management; reviewer access and review; foundational AMA-SPOR; the enterprise and security foundations (IAM/SSO, encryption, backup and restore, audit logging); and structured inspection-report capture. For Marketing Authorization, phase 1 is limited to dossier intake and review. Screening, questions and responses cycles, regulatory decision-making and reliance workflows are outside the Phase 1 scope.
- **Phase 2 — Foundations and Market Authorization (2027).** Subject to AMA's authorization to proceed following the MVP stage-gate, phase 2 will extend the MVP into the core regulatory platform. It will include the RIMS core (configurable workflow engine, AMA internal portal, enterprise integration platform), the full Market Authorization workflow, AfriVigilance integration, billing, security operations (SIEM/SOC/CSPM), the wider productivity roll-out, and full IDMP enrichment and golden-record master data.
- **Phase 3 and beyond (2028+) — future context only.** Future phases may extend the platform to additional regulatory functions including scientific advice, clinical trials, inspections, lab management, licensing as well as advanced analytics and AI capabilities, and continental multi-tenant deployment. These capabilities are not part of the procurement commitment. They are included to ensure that proposed solutions can demonstrate a clear path for future extensibility and scale. Phase 1 architecture shall support future multi-tenancy without fundamental re-design. Activation and operational use of multi-tenancy are planned for a later phase.

A mandatory MVP Stage-Gate governs the boundary. Completion of Phase 1 will be followed by an MVP stage-gate against the defined acceptance criteria and AMA will **determine whether to** proceed with, defer or discontinue with phase 2. Bidders shall therefore provide separate pricing and delivery schedules for Phase 1 and Phase 2. Phase 1 shall be designed and delivered, so its outputs extend into Phase 2 without substantial rework. AMA's commitment at contract award is limited to Phase 1. Mobilization and expenditure for Phase 2 may commence only following AMA's written Authorization to proceed.

Additional information sits in the Annexures. This document is the framework, not the full specification. A substantial part of the detail bidders need is available only in the accompanying Annexures which forms an integral part of this RFP and must be read together with it. The annexures carry a condensed set of submission instructions and questions (B), the system requirements (C), a pricing template (D) and the EOI template (E). Bidders should make sure to submit the required annexures when responding to this RFP.

Process and evaluation. Questions **must be submitted by** 26 August 2026. Consolidated responses are expected to be published on 31 August 2026. A virtual information session **will be held** on 4 September 2026. Demonstrations and interviews are expected to take place from 28 September to 2 October 2026 with award notification expected mid-October 2026. Proposals will be evaluated on component-by-component basis using the weighted evaluation framework. The indicative weighting is: Strategic Fit ~20%, Solution Fit ~50%, Commercial Fit ~30% subject to the mandatory responsiveness and minimum qualification requirements. The evaluation will also consider functional, technical and adoption readiness.

Contracts are concluded with AMA as Client. Garnet Partners Ltd, acting as Contract Management Partner and Fiscal Administrator, will administer milestone payments following AMA's written acceptance of the corresponding deliverables

Data Sheet

This Data Sheet summarizes the key parameters of this procurement. Where a topic is developed elsewhere in the RFP, the relevant section is cross-referenced.

Client	African Medicines Agency (AMA), acting through Garnet Partners Ltd (Contract Management Partner and Fiscal Administrator).
Assignment	Digital Platform for Continental Medicines Regulation, procured in five components (see Chapter 3).
Method of selection	Modular, competitive procurement with weighted evaluation per Chapter 4 (Strategic Fit ~20%, Solution Fit ~50%, Commercial Fit ~30%), subject to a responsiveness check (Section 4.1) and mandatory minimum qualifications (Section 4.2).
Language	Proposals in English; supplementary materials in other AU languages permitted with an English summary (Section 3.7).
Proposal validity	Minimum ninety (90) days after the submission deadline.
Price basis	Prices quoted in United States Dollars (USD); Phase 1 firm and Phase 2 firm / conditional.
Intent to Respond	Required by Friday 26 August 2026 (Section 3.5).
Clarifications	In writing; questions due 26 August 2026; consolidated responses (addendum) published 31 August 2026 (Sections 3.2 and 3.4).
Submission deadline	Friday 18 September 2026 (Section 3.2). Late submissions will not be accepted.
Submission and communication address	Garnet.Tenders@garnetpartners.rw and AMATender@au-ama.africa (administered by Garnet on behalf of AMA).
Evaluation and award	Module-by-module; demonstrations / interviews 28 September - 02 October 2026; notification of award mid-October 2026 (Sections 3.2, 3.8 and 3.9).
Mandatory documents	As listed in the Letter of Invitation and Section 4.2.

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Definitions and Abbreviations

Where the same abbreviation has more than one meaning in this document, both are listed and disambiguated by context.

Abbreviation	Definition
ADR	Adverse Drug Reaction
AfCFTA	African Continental Free Trade Area
AI	Artificial Intelligence
ALP	AMA-Listed Product
AMA	African Medicines Agency
AMDF	African Medicines Development Forum
AMQF	African Medicines Quality Forum
AMRC	African Medicines Regulators Conference
AMRH	African Medicines Regulatory Harmonization
API	Active Pharmaceutical Ingredient
API (digital)	Application Programming Interface
AS2	Applicability Statement 2 (secure data transfer protocol)
AU	African Union
AUC	African Union Commission
AUDA-NEPAD	African Union Development Agency – NEPAD
AVAREF	African Vaccine Regulatory Forum
BAFO	Best and Final Offer
BI	Business Intelligence
CapEx	Capital Expenditure
CT	Clinical Trials
CTA	Clinical Trial Application
CTD	Common Technical Document
DG	Director General
DISD	Data Integration and Signal Detection
DMS	Document Management System
EA	Enterprise Architecture
EAC	East African Community
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
EMP	Evaluation of Medicinal Products
MVP	Expression of Interest
ERP	Enterprise Resource Planning
FDA Ghana	Food and Drugs Authority of Ghana
FR	Functional Requirement
GBT	Global Benchmarking Tool
GCP	Good Clinical Practice
GMP	Good Manufacturing Practices

Abbreviation	Definition
HSA	Health Sciences Authority (Singapore)
IAM	Identity and Access Management
IBAR	Inter-African Bureau for Animal Resources
ICER	Individual Case Safety Report
IDMP	Identification of Medicinal Products (ISO standard)
IGAD	Intergovernmental Authority on Development
IMS	Integrated Regulatory Information System
IP	Intellectual Property
IPASA	Innovative Pharmaceutical Association South Africa
ITSM	IT Service Management
KYC	Know Your Customer
LIMS	Laboratory Information Management System
LoQ	List of Questions
MA	Market Authorisation
MCAZ	Medicines Control Authority of Zimbabwe
MDM	Master Data Management
MFA	Multi-Factor Authentication
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
ML1–ML4	WHO Maturity Level 1 through Maturity Level 4
MRH	Medicines Regulatory Harmonisation
MS	Market Surveillance
NeeS	Non-eCTD electronic Submission
NEPAD	New Partnership for Africa's Development
NFR	Non-Functional Requirement
NGO	Non-Governmental Organisation
NOMCoL	Network of Official Medicines Control Laboratories
NRA	National Regulatory Authority
OMS	Organisation Management Service (SPOR)
OpEx	Operating Expenditure
PANVAC	Pan African Veterinary Vaccine Centre
PMPA	Pharmaceutical Manufacturing Plan for Africa
PMS (1)	Post-Market Surveillance
PMS (2)	Product Management Service (SPOR)
POPIA	Protection of Personal Information Act (South Africa)
PV	Pharmacovigilance
QA	Quality Assurance
QMS	Quality Management System
RACI	Responsible, Accountable, Consulted, Informed
RCORE	Regional Centres of Regulatory Excellence
REC	Regional Economic Community

Abbreviation	Definition
RFP	Request for Proposal
RIMS	Regulatory Information Management System
RISP	Regulatory Information Sharing Portal
RMS	Referentials Management Service (SPOR)
S3 / AU-3S	Smart Safety Surveillance
SADC	Southern African Development Community
SAHPRA	South African Health Products Regulatory Authority
SF	Substandard and Falsified (medicines)
SI	Systems Integrator
SLA	Service Level Agreement
SMS	Substance Management Service (SPOR)
SOC 2	Service Organization Control 2 (security audit)
SOPs	Standard Operating Procedures
SOW	Statement of Work
SPOR	Substances, Products, Organisations, Referentials (EMA master data)
SSO	Single Sign-On
TC	Technical Committee
TCO	Total Cost of Ownership
TMDA	Tanzania Medicines and Medical Devices Authority
T&M	Time and Materials
TWGs	Technical Working Groups
URS	User Requirements Specification
US FDA	United States Food and Drug Administration
UX	User Experience
WAEMU	West African Economic and Monetary Union
WAHO	West African Health Organisation
WHO	World Health Organization
WHO-AFRO	WHO Regional Office for Africa
WLA	WHO-Listed Authority
ZaZiBoNa	Zambia, Zimbabwe, Botswana, Namibia joint regulatory initiative

Chapter 1 - AMA Context

1.1 About the African Medicines Agency

The African Medicines Agency (AMA) was established by the Assembly of Heads of State and Government of the African Union at its 32nd Ordinary Session on 11 February 2019 in Addis Ababa, as a continental institution mandated to strengthen the regulation of medical products across Africa.

AMA operates within a regulatory ecosystem that has made meaningful progress over the past decade through initiatives such as AMRH, AVAREF and regional harmonization programs. While these efforts have demonstrated the effectiveness of joint assessments, coordinated inspections and regulatory collaboration, the overall system landscape remains fragmented and incomplete, characterized by duplication of effort, uneven regulatory capacity, and inconsistent timelines and data-sharing across AU Member States.

Strategic role of AMA

AMA's strategic positioning is explicitly defined as a continental coordinator, system orchestrator, and enabler of stronger National Regulatory Authorities (NRAs), rather than a centralized regulator replacing them. Its mandate is to address structural inefficiencies that cannot be effectively resolved at national or regional level alone, by enabling coordinated regulatory activities, harmonized standards, and reliance-based mechanisms across the continent.

In this model:

- NRAs retain sovereign decision-making authority
- AMA provides scientific coordination, shared services and continental standards
- regulatory processes are increasingly aligned through reliance, work-sharing and harmonization

This reflects a deliberate strategic shift toward a federated, reliance-based regulatory system, where value is created through coordination and reduction of duplication, rather than centralization.

Vision

AMA's long-term direction is anchored in a clearly defined strategic framework:

- **Vision:** enabling a healthy, self-reliant Africa with access to quality, safe and efficacious medical products supported by trusted, harmonized regulatory excellence
- **Mission:** improving access to medical products by coordinating continental regulatory activities, setting harmonized standards and enabling efficient reliance in support of NRAs and Regional Economic Communities (RECs)
- **5-year ambition:** becoming a credible, operational continental regulatory coordinator with measurable public health impact and a clear path toward financial sustainability

This ambition is underpinned by progression from initial coordination and credibility-building toward a mature, widely adopted continental regulatory system.

Strategic principles guiding AMA

AMA's strategy is built on four core principles that shape both its operating model and scope of activity:

- **Independent, science-driven and credible:** ensuring trust through rigorous, transparent, and evidence-based decision-making
- **Inclusive, cooperative continental orchestration:** connecting the regulatory ecosystem and aligning roles across NRAs, RECs and partners
- **Public health impact first:** prioritising faster and more equitable access to quality-assured products
- **Non-duplicative, value-adding action:** focusing on activities that reduce fragmentation, fill critical gaps and improve efficiency at continental level

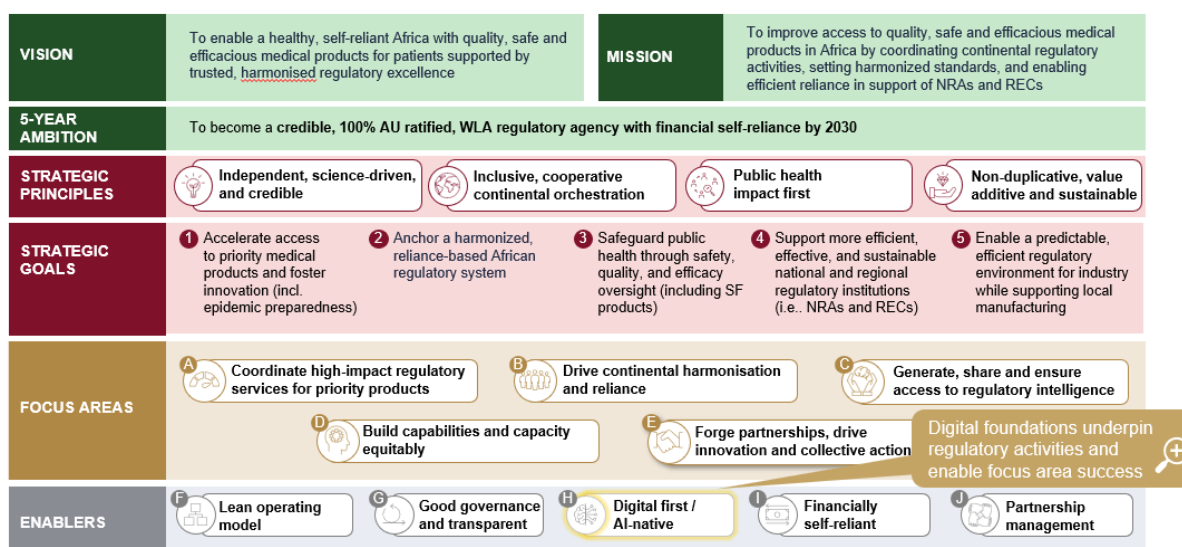
Together, these principles reinforce AMA's role as a complementary layer to existing regulatory systems, not a replacement.

1.2 Mandate, Member States, and Continental Operating Model

The scope of the African Medicines Agency (AMA), as defined in the AMA Treaty, spans the full lifecycle of regulatory activities, including:

- Market authorization including joint product evaluation
- Clinical trial oversight
- Regulatory inspections and laboratory testing
- Pharmacovigilance and post-market surveillance
- Development of harmonized standards and regulatory policies
- Capacity building and strengthening of NRAs across the continent

The AMA strategy highlights digital as a critical enabler



3

Member States

AMA operates within the African Union framework, with a long-term ambition to serve all 55 AU Member States through a shared regulatory model and interoperable systems.

Participation in AMA is driven by treaty ratification with progressive onboarding of Member States.

The AMA model is anchored in joint assessments and reviews by member states coordinated by AMA with regulatory reliance mechanisms to reuse scientific outputs.

Continental Operating Model

AMA adopts a continental, reliance-based operating model, characterized by:

- Central coordination by AMA, including dossier intake, allocation, and scientific opinion. This coordination allows for joint collaborations and shared work platforms between AMA and the NRA's
- Execution distributed across NRAs, leveraging local expertise and existing capacities
- Dual-track model, where:
 - AMA handles continental-level procedures via a central pathway
 - NRAs continue to operate national processes independently (with reliance on AMA where applicable)

1.3 High-level AMA operationalization and initial continental listing exercise

As AMA transitions from strategic design to execution, its operationalization is structured as a phased, capability-driven process aimed at delivering early tangible value while building the foundations for long-term continental scale.

The initial phase of operationalization focuses on launching high-impact regulatory services supported by foundational digital capabilities, while progressively establishing the broader AMA digital ecosystem. This approach reflects the principle that AMA must demonstrate credibility and value through execution of priority services before scaling to full regulatory coverage.

As part of its initial operationalization, AMA is preparing to launch a continental listing exercise (Jan 2027 – see details in chapter 2), planned as a pilot initiative to validate its role in coordinating cross-border market authorization activities.

The pilot is designed to:

- Enable single dossier submission by sponsors
- Support joint scientific assessment and coordinated review processes
- Facilitate regulatory reliance across NRAs

This exercise represents a critical step in testing AMA's federated operating model in practice. The continental listing exercise provides the initial use case for vendor proposals.

The MVP scope and the phasing model are defined in Section 2.5.

1.4 Procurement Ownership, Funding, and the Role of Garnet Partners Ltd

Garnet acts as Contract Management Partner and Fiscal Administrator for AMA procurements, including this Request for Proposal. Accordingly, this RFP is issued by AMA through Garnet Partners Ltd: the procurement is owned by AMA and is executed and administered by Garnet on behalf of AMA.

The division of roles is as follows and applies from this introduction through to contract award, delivery, and payment:

- AMA (the Client and process owner) - defines the requirements and Terms of Reference, evaluates proposals through its Evaluation Committee, makes all award decisions, signs the resulting contracts as the Client, provides delivery governance, and formally accepts (or rejects) all deliverables. Nothing in this RFP or in any resulting contract transfers AMA's decision-making authority, ownership of the assignment, or institutional responsibility to Garnet.
- Garnet Partners Ltd (Contract Management Partner and Fiscal Administrator) - administers the procurement process on AMA's behalf (publication, receipt of intents to respond and proposals, clarifications and addenda, and process record-keeping), provides contract administration and coordination support, verifies invoices and supporting documentation for financial accuracy, and processes milestone payment following AMA's written acceptance of the relevant deliverables. Garnet has no authority to approve technical deliverables, evaluation outcomes, or contract amendments on AMA's behalf.

In practical terms for bidders: all communications, questions, and submissions under this RFP are made through the channels administered by Garnet on behalf of AMA; awarded contracts are concluded with AMA as the Client, with Garnet joining in its contract-management and fiscal-administration capacity; invoices are addressed to AMA with a copy to Garnet; and payments are released by Garnet only after AMA's written acceptance of the corresponding milestone or deliverable. Final authority for the acceptance of deliverables, approval of payments, and all other decisions affecting a resulting contract remains vested exclusively in AMA (its Director General or a formally delegated officer).

Chapter 2 - AMA Digital Strategy Overview

2.1 Digital Strategy Overview

The AMA Digital Strategy aims to establish the Agency as a digitally enabled, continent-wide regulatory backbone, capable of delivering faster, safer, and more consistent regulatory outcomes across Africa – based on best-in-class approaches and advanced technologies including AI, GenAI etc.

Vendors should be familiar with AMA's digital strategy and be able to answer specific questions about how their solution(s) align with the strategy described. Vendors are encouraged to challenge AMA's strategic assumptions if they believe an alternative approach is favorable but must provide strong justification aligned to AMA's digital guiding principles and objectives. Chapter 2 contains key synthesis of AMA's digital strategy most applicable to this RFP.

AMA's digital objectives:

1. **Define a shared North Star** for AMA's Digital Strategy that articulates how digital enables AMA's mandate, strengthens regulatory trust, and supports delivery with NRAs and RECs.
2. **Assess the current digital landscape** across NRAs and AMRH assets, identify priority gaps and readiness constraints, and clarify how existing capabilities fit the AMA strategy.
3. **Describe the target end- state** for AMA's digital foundation, including core regulatory platforms and the principles that will govern interoperability, data, cybersecurity, and responsible AI.
4. **Prioritize strategic initiatives and define a phased roadmap**, with clear governance and decision rights to ensure execution from strategy through implementation.
5. **Highlight immediate MVP** needs and implementation requirements to support a continental listing process.

AMA's digital guiding principles:

1. Strategy and capability-led, not technology-led
2. Build on existing systems, minimize custom development
3. Build with Africa-centric design
4. Ensure transparency and accountability
5. Source attainable, cost-effective and sustainable solutions
6. Promote trust through robust cybersecurity and data governance
7. Focus on AMA capabilities, plan with scalable, interoperable design
8. Maximize NRA/REC compatibility, adoptability and optionality

Key principles driving AMA's digital procurement:

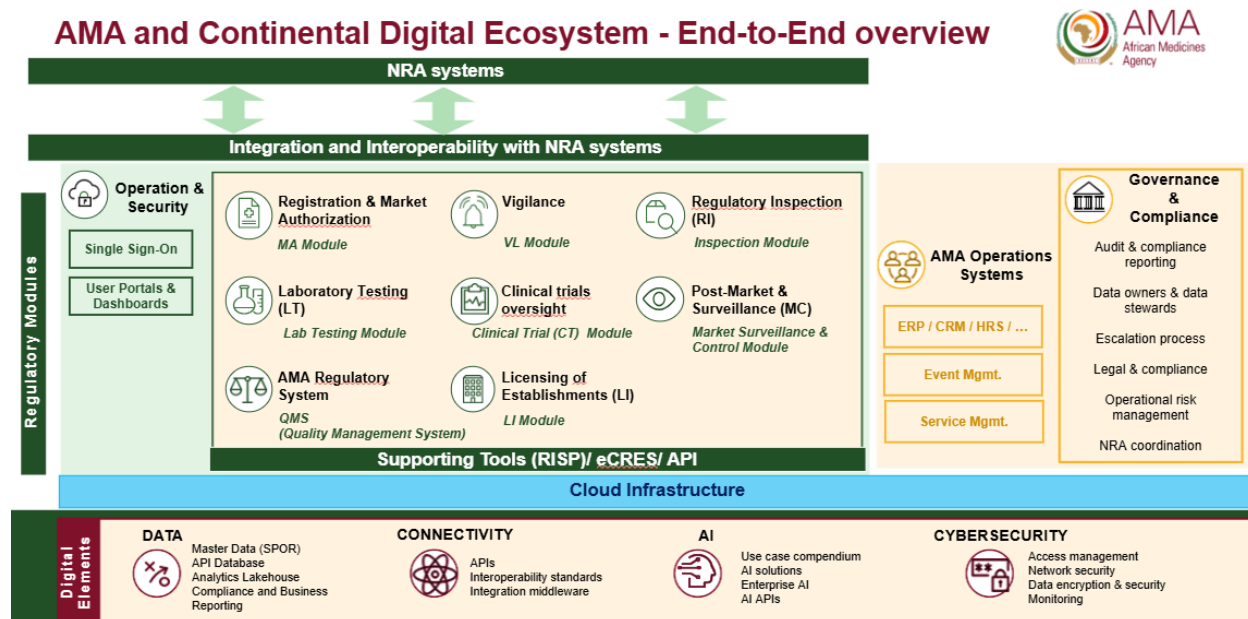
1. **Sustainability.** Solutions must be affordable to run and support beyond the initial build period, with transparent total cost of ownership, a preference for open-source components where they meet AMA's functional, security and support requirements, and skills transfer that allows AMA to operate the platform with its own team.
2. **Digital first.** Regulatory processes are to be delivered digitally end to end, from sponsor submission through review and decision, rather than digitizing paper-based steps or relying on manual workarounds and offline document exchange.
3. **Configurability.** Capabilities must be delivered predominantly through configuration of proven products, including low-/no-code workflow configuration, so that AMA and future NRA tenants can adapt processes without bespoke redevelopment.
4. **Future enablement.** Phase 1 must be built so that later phases extend it without rework, using open standards and modular, interoperable architecture that supports additional regulatory functions, analytics and AI, and continental multi-tenant scale-up.

2.2 Target-State Capability Model

The target-state capability model is implemented through a unified, layered digital platform rather than a collection of standalone systems.

While AMA's mandate spans multiple regulatory functions, these capabilities are not delivered as independent solutions, but as integrated modules configured and operated on top of a shared platform composed of common channels, workflow and document services, data foundations, and enterprise capabilities. The target system integrating all the different Regulatory Capabilities is called the AMA RIMS (Regulatory Information Management System).

This platform-based approach enables consistency, scalability, and interoperability across regulatory capabilities, while supporting AMA's federated operating model and future expansion to multiple NRAs.



2.2.1 Core Regulatory Capabilities

The sections below outline the key components of AMA's digital infrastructure and how they interact.

Shared workflow engine (model)

The workflow engine is central: a Market Authorization and a GMP inspection run through the same engine, with the differences living in configurable rules and process steps. AMA places particular value on low-/no-code workflow configurability (both for AMA and future NRA tenants) – for example, adding a review cycle for a particular NRA - so the platform can be tailored or adapted without rebuilding it.

AMA-SPOR (master data)

At the center of the data architecture is AMA-SPOR, AMA's authoritative master-data layer and single source of truth, organized as four services: Substance (SMS), Product (PMS), Organization (OMS) and Referential (RMS) management. AMA-SPOR is aligned to the ISO IDMP family (exposed via HL7 FHIR R5 and APIs for data interoperability between modules) and is built fresh from authoritative sources - sponsor submissions, WHO feeds, and existing African Union assets such as the AMRH API Database - rather than migrated from a legacy system. At MVP it will be deliberately foundational, establishing the authoritative record and its governance for organizations, products, substances and core terminologies, and will be enriched toward full IDMP in later phases (see Section 2.5).

A single sponsor gateway and centralized access control

AMA requires that sponsors interact with AMA through a single channel. The sponsor gateway is therefore the one external front door for industry (across all submission types), handling account management, eCTD

submission, fee payment, status tracking and communications. Internal users work in the AMA Portal. Both sit behind a centralized Identity and Access Management layer - single sign-on with role- and attribute-based access control - that governs every user and module, provides full audit trails, and is designed to support per-NRA tenant isolation (attribute-based access control and row-level security) once the platform scales.

Interoperability and integration

The platform outlines a hybrid integration model: REST APIs for queries and lookups, an event mesh for state changes and notifications, and secure file transfer (AS4 for eCTD submissions; SFTP as a fallback). It integrates with, rather than replaces, existing continental systems - notably AfriVigilance (vigilance), and the AMRH API Database (substance data) - and adopts international standards and authoritative vocabularies by reference.

A continental, multi-tenant RIMS - AMA first, scaling outward

AMA's target is a continental, multi-tenant Regulatory Information Management System (RIMS): one platform that AMA operates for itself, with the option for NRAs to adopt it as their own tenant over time. The immediate focus is standing up AMA's own capabilities. Multi-tenancy is architected from the outset - so no costly rebuilding is needed later - but is activated in a later phase (see Section 2.5). To achieve this, AMA is focused on the sustainability, scalability, and configurability of its target-state platforms. NRA sovereignty is preserved throughout: NRA participation is opt-in, and NRAs that do not opt in continue to exchange data with AMA through simple APIs.

2.2.2. System integration

Given AMA's lean internal team and a wide variety of regulatory capabilities with AMA's mandate, AMA intends to engage a System Integrator (SI) as prime delivery partner. The SI will own end-to-end integration and governance, tie the shared foundations together (gateway, portal, eCTD, workflow engine and data foundations), and coordinate the vendor(s) to establish the regulatory core capabilities. AMA values flexibility and the avoidance of vendor lock-in, and will consider licensed, open-source and AMA-owned arrangements component by component (the eCTD, for example, is expected to be licensed).

2.2.3 Cloud and Infrastructure

In the target-state platform model, cloud and infrastructure form part of the enterprise foundations and enable the platform to scale securely across geographies, users, and regulatory domains.

AMA's digital platform is designed using a cloud-first approach to enable scalability, flexibility, and cross-border collaboration. The cloud strategy supports the federated operating model by enabling centralized coordination while allowing distributed participation across AU Member States.

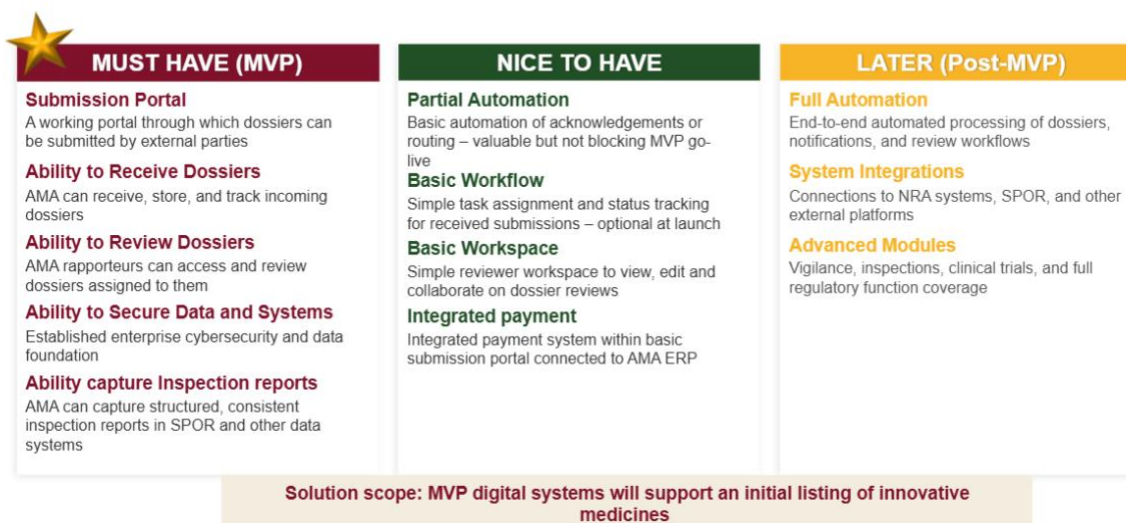
2.3 MVP Overview: Components, Timeline, and Delivery Approach

Objective of the MVP

The Expression of Interest (EOI), positioned as the Submission Platform MVP, represents a critical step in AMA's digital transformation, focused on enabling core regulatory workflows – most notably submission intake and tracking.

What Success Looks Like for MVP

Success is a working submission platform – lean scope, on-time delivery, ready to grow

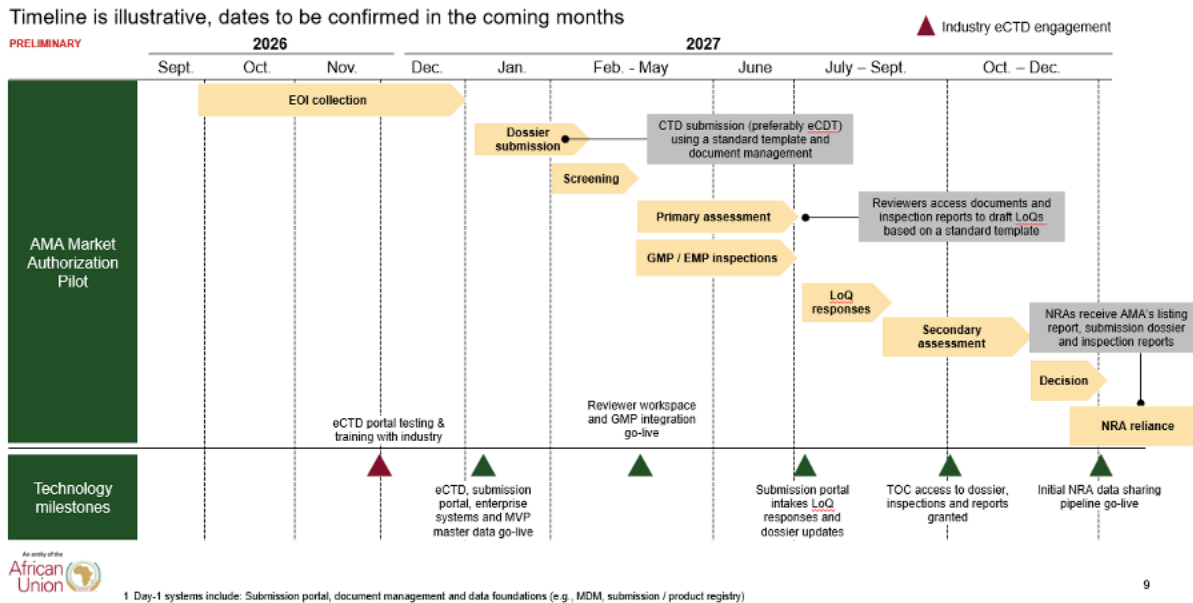


Scope and Components

AMA's MVP is scoped to enable AMA initial Market Authorization exercise starting with the receipt of dossiers in January 2027. An overview of AMA's proposed MVP timeline is shown below.

Preliminary continental listing timeline

Timeline is illustrative, dates to be confirmed in the coming months



Vendors are expected to propose implementation plans that align to AMA's outlined timeline below or detail where they think updates are needed. Vendors are expected to specify the scope they need to deliver to meet each of these regulatory milestones. AMA's MVP implementation is phased, and as such, different regulatory capabilities will be required based on their phased needs. Vendors are expected to align their implementation plans with this phasing.

AMA's MVP scope is deliberately lean: receive and securely hold dossiers, let reviewers access and review them, and establish the data and security foundations everything else will build on. Complete AMA RIMS (enabling all core regulatory capabilities mentioned above), broad automation and additional regulatory modules are targeted for a later phase.

Capability	What is needed at MVP
Sponsor gateway	The single external front door for industry: sponsors register and manage accounts and submit applications. Integrated fee payment is desirable but not critical for early addition. (End of Jan 2027)
eCTD submission & document management	Secure, seamless eCTD dossier intake and validation (e.g., AS4 over HTTPS), and the receipt, storage, versioning and tracking of dossier documents. (End of Jan 2027)
Reviewer access & review	AMA rapporteurs and assessors can access assigned dossiers and conduct their review. (End of March 2027)
Foundational AMA-SPOR	Targeted master data for organizations, products and substances (including WHO sources) and core terminologies, with basic governance. (Vendor to define MVP data domains to be completed by end of Jan 2027)
Enterprise & security foundations	Centralized identity & access (SSO, RBAC), cybersecurity, cloud hosting, backup / disaster recovery, and audit logging. (End of Jan 2027)
Structured inspection report capture	Ability to capture consistent, structured GMP / inspection reports into AMA's data systems. (End of April 2027)

2.4 Stakeholders, User Populations, and Language Coverage at MVP (Includes Indicative Sizing and Volume Assumptions)

Stakeholder Landscape

Stakeholder Group	Role in the AMA Ecosystem	Description	Indicative Population
National Regulatory Authorities (NRAs)	Core regulatory participants	Contribute scientific expertise, conduct assessments, participate in joint reviews, and enable reliance-based regulatory decisions	~55 NRAs (one per AU Member State, varying size and maturity)
Regional Economic Communities (RECs)	Regional coordinators	Facilitate harmonization efforts, coordinate regulatory activities, and align standards across groups of countries	~8 RECs across Africa
Pharmaceutical industry (manufacturers, sponsors)	External applicants / regulated entities	Submit applications, respond to regulatory queries, and interact with AMA throughout the product lifecycle	Hundreds to thousands of organizations across local and global markets
International partners and regulatory agencies	Technical and funding partners	Provide technical guidance, capacity building, funding support, and alignment with global regulatory best practices	Dozens of partners (e.g., international agencies, donors, regulators)
Internal AMA teams	Central coordination body	Perform coordination, oversight, and execution of AMA regulatory services and operations	Yr 1: ~30 people Yr 5: ~100-200 people
AMA scientific committees and experts	Scientific reviewers and advisors	Conduct assessments, provide expert opinion, and support decision-making processes across modules	Hundreds of experts across disciplines and Member States
Patients and the general public	End beneficiaries	Benefit from improved access to safe, effective, and high-quality medical products and increased transparency of regulatory processes	~1.4 billion people across Africa

User Populations

The below table show the User Groups . It should be noted that the users will gradually increase over time as the system is scaled through the Phases as outlined in this RFP. The table below shows only the estimated users during Phase 1 herein referred as the Minimum Viable Product (MVP).

The MVP platform is expected to serve multiple user groups, including:

User Group	Role in the Platform	Key Activities and Responsibilities	Interaction with the System	Estimated users
Regulatory reviewers and scientific experts	Core execution actors	Perform scientific assessments, review dossiers, evaluate data, contribute to regulatory decisions and joint reviews	Access reviewer workspace, annotate dossiers, collaborate with other reviewers, generate assessment outputs and reports	200
NRA representatives	Federated regulatory participants	Participate in joint reviews, provide country-specific input, contribute to reliance-based decisions, adopt or adapt AMA outcomes at national level	Access shared dossiers and reports, participate in workflows (active or consultative), receive outputs and submit feedback; reliance-only NRAs may participate consultatively rather than in a joint review	55
Pharmaceutical industry users (manufacturers, sponsors)	External applicants	Submit regulatory dossiers, respond to questions (e.g. LoQs), track application status, interact with AMA throughout the product lifecycle	Use submission portal for dossier uploads, track progress, respond to queries, receive notifications and decisions	30
AMA leadership	Strategic oversight and decision-making	Monitor regulatory performance, review key metrics and dashboards, support strategic decision-making, oversee programme execution and institutional performance	Access executive dashboards and analytics, review performance indicators and reports, monitor program progress and outcomes, receive alerts and summaries of key activities	10
AMA operational staff	Central coordinators	Manage submissions, coordinate workflows, assign reviewers, monitor process progress, ensure timely execution of regulatory activities	Use workflow management tools, manage queues and tasks, monitor deadlines, coordinate communication across actors	10
AMA administrative and IT users	Platform operators and administrators	Configure system settings, manage users and roles, maintain platform configuration, ensure system availability and data integrity	Access admin interfaces, manage permissions (IAM), configure workflows and templates, oversee system operations	5
AMA scientific committees	Decision and advisory bodies	Review consolidated assessments, provide expert opinions, validate outcomes, contribute to final recommendations	Access review summaries, participate in decision workflows, approve or comment on assessments	100
International partners and advisors	External support and oversight	Provide technical input, support capacity building, align with global standards, contribute to regulatory strengthening efforts	Access selected data and reports (where permitted), provide input through defined collaboration mechanisms	-
Patients and the public	End beneficiaries	Benefit from improved access to safe and	Indirect interaction; may access public information	Open access to

User Group	Role in the Platform	Key Activities and Responsibilities	Interaction with the System	Estimated users
		effective medicines and increased transparency of regulatory processes	portals, safety updates, and regulatory decisions	public systems

Given the federated model, user engagement will vary:

- Core AMA workflows are centrally coordinated, with NRA reviewers actively contributing to key regulatory activities such as assessments and joint reviews
- Broader participation from NRAs is enabled through reliance mechanisms and flexible access models (e.g., view-only or active participation)

Indicative Sizing and Complexity Drivers

The design of the AMAs digital solutions must consider:

- Up to 55 NRAs with heterogeneous digital maturity
- Mixed landscape of manual, file-based, and API-enabled systems
- Variable volumes of submissions and regulatory activities across countries
- Need for scalable integration patterns (e.g., API vs. file-based exchange)

These factors create a complex, highly variable operating environment requiring flexibility and adaptability in system design.

Language Coverage

As a continental institution, AMA must operate across multiple working languages aligned with the African Union context.

The MVP phase will prioritize support for English and French, while ensuring the platform is designed to scale to all six official African Union languages over time.

2.5 Phasing, Scope Boundaries and Staged Commitment

Phasing and staged award. This procurement is awarded as a single engagement covering Phase 1 (MVP) and Phase 2, with a mandatory MVP Stage-Gate governing continuation (see Section 2.5). Respondents must:

- Price Phase 1 and Phase 2 as separate, self-contained schedules.
- Acknowledge that continuation to Phase 2 is at AMA's discretion following the gate (proceed, defer or discontinue), with Phase 2 mobilization beginning only on AMA's authorization to proceed;
- Design Phase 1 so its outputs extend into Phase 2 without rework, and show how the architecture supports Phase 3+ functions as context;
- Treat all Phase 3+ scope as non-binding context; and
- State, per module, which phase(s) they are bidding for and how their solution integrates at each phase boundary.

AMA's digital platform is delivered in phases, building AMA's own capabilities first and scaling outward. **This RFP covers the first two phases; later phases are described for context and extensibility only.** See AMA's digital strategy for additional information on the phased roadmap

Phase 1 - MVP (early 2027). A deliberately lean submission platform and enterprise setup: the sponsor gateway; secure eCTD (ICH M8 / v4.0) intake, validation and document management; reviewer access and review; foundational AMA-SPOR; the enterprise and security foundations (identity and access, encryption, backup and restore, and audit logging); and structured inspection-report capture. **Market Authorization at MVP is limited to intake and review**, capturing and tracking MA/listing requests and enabling reviewers to access and review dossiers. It does **not** include the assessment of workflow (screening, list-of-questions cycles, decision or reliance).

Phase 2 - Foundations and Market Authorization (2027). The RIMS core (configurable workflow engine, AMA internal portal, the enterprise integration platform including the API gateway and event mesh, and

initial NRA integrations), the full Market Authorization workflow, AfriVigilance integration, billing, security operations (SIEM/SOC/CSPM), the broader productivity roll-out, and the broader data foundations (full IDMP enrichment and golden-record master data).

Phase 3 and beyond (2028+). Additional regulatory functions (inspections, clinical trials, lab management, licensing), advanced analytics and AI, and continental multi-tenant scale-up. These appear in this RFP as **roadmap and architectural context only. They are not part of the priced or committed scope** and should be treated solely as the basis for demonstrating extensibility.

Staged commitment. Award under this RFP covers Phase 1 and Phase 2. **Continuation to Phase 2 is subject to a mandatory MVP Stage-Gate:** at the completion of Phase 1, AMA will assess the delivered MVP against defined acceptance criteria and decide to **proceed, defer, or discontinue**. Phase 2 mobilization and expenditure are authorized only on a decision to proceed.

Phasing at a Glance:

The following maps each capability to its phase. It is illustrative of Section 2.5; please reference Section 2.5, or the AMA strategy for further phasing details

Capability / module	Phase
Sponsor gateway (register, manage account, submit)	Phase 1 (MVP)
eCTD v4.0 intake, validation, document management	Phase 1 (MVP)
Reviewer access & basic review	Phase 1 (MVP)
Market Authorization – intake & review only	Phase 1 (MVP)
Foundational AMA-SPOR (SPOR Tier 0)	Phase 1 (MVP)
Enterprise & security foundations (IAM/SSO, encryption, backup/restore, audit logging)	Phase 1 (MVP)
Structured inspection-report capture	Phase 1 (MVP)
Access & usability views	Phase 1 (MVP)
Basic status workflow / task assignment	Phase 2 – MVP nice-to-have
Integrated fee payment	Phase 2 – MVP nice-to-have
Configurable workflow engine	Phase 2
AMA internal portal (full build-out)	Phase 2
Market Authorization – full workflow (screening, LoQ, decision, reliance)	Phase 2
Data foundations: full IDMP enrichment, golden-record MDM, governance operating model	Phase 1/2 (Phase 1: MVP foundations need to intake dossiers, inspections and track regulatory outcomes with a plan to scale)
Enterprise integration platform: API gateway + event mesh	Phase 1/2 (Phase 1: MVP foundations need to manage basic data exchange between MVP components)
Security operations: SIEM / SOC / CSPM / DLP	Phase 2
ITSM platform + CAB + SLA framework + problem mgmt/CMDB	Phase 2 – (Phase 1 for SLA framework for MVP components)
Productivity roll-out (M365 beyond identity/security)	Phase 2
AfriVigilance (HaloPV) integration – E2B(R3)	Phase 2
Initial NRA integrations (ML3)	Phase 2
Billing (fee schedules, invoicing, reconciliation) + ERP integration	Phase 2
Master-data intake workflows + front-end view	Phase 2
Expert management (eCRES integration)	Phase 2
Scientific Advice / Clinical Trials / Lifecycle Mgmt / Inspections module / Lab Mgmt / Licensing	Phase 3+ (context)
Analytics / BI / data products / AI	Phase 3+ (context)
Multi-tenant NRA onboarding	Phase 3+ (context) – architected at MVP, activated later
QMS	Cross-cutting

Chapter 3 - Selection Process and Key Dates

This chapter describes the end-to-end procurement process AMA will follow to select vendors for the MVP Digital Platform. This chapter sets out the rules of engagement, key milestone dates, permissible communications, and the conditions that govern proposal submission, evaluation, and award.

Consistent with Section 1.4, this selection process is owned and decided by AMA and is administered end-to-end by Garnet Partners Ltd. References in this chapter to procurement administration (publication, clarifications, addenda, receipt of submissions, and process correspondence) are executed by Garnet on AMA's behalf; all evaluation and award decisions are made by AMA.

Vendors are expected to propose an integrated solution covering the full scope of the Enterprise Setup module. Partial responses (e.g. limited to specific capabilities such as IAM or cloud infrastructure) must be clearly identified and justified. AMA reserves the right to evaluate integrated and component-based proposals depending on vendor strengths and delivery model.

3.1 Procurement Approach Overview

AMA will conduct a modular, competitive procurement organized around a single Request for Proposal (RFP). The RFP is structured into five discrete components, each representing a distinct functional domain of the MVP digital platform. This modular design reflects AMA recognition that no single vendor is likely to offer best-in-class capability across all five modules.

Award under this RFP covers Phase 1 (MVP) and Phase 2 as a single engagement, with continuation to Phase 2 governed by a mandatory MVP Stage-Gate at which AMA may proceed, defer or discontinue. The phasing model is set out in Section 2.5

Respondent obligations are set out in the Guide for Respondents.

The five components are:

- **Component 1 – eCTD v4.0:** Submission portal and electronic Common Technical Document handling for industry submissions and reviewer workflows.
- **Component 2 - Data Standards & Integrations:** Master data, terminologies, and interoperability across regulatory systems.
- **Component 3 - Enterprise Setup:** Identity, cloud, access, hosting, security, and operational requirements that underpin the platform.
- **Component 4 - Systems Integration:** Integration approach, delivery model, and responsibilities of the Systems Integrator.
- **Component 5 - Portal & RIMS:** Regulatory Information Management - evaluated as optional scope, to be assessed independently.

AMA's procurement approach: Vendors may bid for one or more modules, individually or as consortia/prime-sub teams. AMA evaluates proposals module by module against a pre-published rubric and awards each module to the strongest qualified bidder; cross-module partnerships are welcomed but not required.

Systems Integrator (SI) Strategy

AMA strongly recommends that bidders for component 4 demonstrate the capacity to serve as a prime delivery partner (Systems Integrator), data standards and integration partner and Enterprise setup partner. AMA is aware of the significant delivery risks that arise in multi-vendor digital programs without a dedicated SI. The SI will be responsible for:

- Coordinating delivery across all module vendors.
- Providing structured change management and user onboarding.
- Ensuring adherence to quality, timelines, and budget.

- Managing escalation pathways and RACI structures.
- Providing ongoing managed services and hyper care support post-launch.

AMA will assess Component 4 proposals on two things: the vendor's proven SI capability, and how they will coordinate multiple vendors.

3.2 Schedule of Events

The table below sets out the procurement milestone schedule for this procurement. All dates are binding unless AMA issues a formal written amendment via the official procurement portal.

Milestone	Date	Responsible party
RFP launched and published	Monday 17 Aug 2026	AMA Procurement
Vendor intent to bid	Wednesday 26 Aug 2026	Bidding vendors
Vendor questions and clarifications due	Wednesday 26 Aug 2026	Bidding vendors
AMA consolidated responses to questions posted (addendum)	Monday 31 Aug 2026	AMA Procurement
RFP information session (virtual)	Friday 04 Sep 2026	AMA Procurement / Digital Team; interested vendors
Proposals (RFP responses) due	Friday 18 Sep 2026	Bidding vendors
Demonstration requirements shared with responding vendors	Week of Sep 21 st 2026	AMA Procurement
Vendor demonstrations / interviews	Monday 28 Sep - Friday 02 October 2026	Responding vendors
Notification of award(s)	Mid-October 2026	AMA Procurement

Note: milestones shown above as the responsibility of "AMA Procurement" are executed administratively by Garnet Partners Ltd on behalf of AMA. All dates, addenda, and award decisions are approved by AMA.

3.3 Pre-Proposal information session and Communications Protocol

AMA will hold an RFP information session on **04 September 2026**, following publication of the consolidated responses to vendor questions (31 August 2026). The information session will be held virtually to provide more clarity and insights on this project. Attendance is not mandatory but strongly recommended.

Communications Protocol

To ensure fairness and prevent any vendor from receiving preferential information, the following communications protocol is in force from the date of RFP publication:

- All questions and clarifications must be submitted in writing to the designated procurement contact, which is administered by Garnet Partners Ltd on behalf of AMA.
- Oral communications with AMA staff regarding this RFP are not permitted and will not be binding.
- AMA written responses will be issued in AMA's name, distributed by Garnet Partners Ltd, and shared with all registered bidders simultaneously via formal addenda.
- Any vendor who circumvents this protocol may be disqualified from the process.

3.4 Questions, Clarifications, and Addenda

Vendors may submit written questions on any aspect of this RFP. Questions should be submitted through the designated procurement portal or email address provided in the accompanying cover letter; this channel is administered by Garnet Partners Ltd on behalf of AMA. Vendor questions are due by 26 August 2026. AMA will compile all questions and publish a consolidated Q&A document as a formal addendum by 31 August 2026 (see Section 3.2).

AMA reserves the right to issue addenda at any point during the procurement process. All addenda become part of the RFP and must be incorporated into any proposal submitted. It is the vendor's responsibility to monitor the procurement portal for addenda.

3.5 Intent to Respond and Component-Level Bid Declarations

AMA requires that all prospective bidders register an Intent to Respond (ITR) by 21 August 2026 (see Section 3.2). Registration serves two purposes:

- It allows AMA to manage the evaluation workload and provision adequate panel resources.
- It confirms the module(s) for which each vendor intends to bid, enabling AMA to assess panel composition needs.

An ITR is non-binding and does not preclude a vendor from subsequently bidding on additional modules or withdrawing from the process. However, proposals submitted without a prior ITR will not be accepted.

Vendors must declare, at ITR stage, whether they are bidding as a single entity, a prime with sub-contractors, or as part of a consortium. Changes to bidding arrangements after the ITR deadline must be approved by AMA in writing.

3.6 Partnering, Prime/Sub, and Consortium Rules

AMA actively encourages vendors to form partnerships and consortia where this strengthens their capability to deliver against module requirements. The following rules apply:

- A lead (prime) vendor must be clearly identified for each module bid and will be AMA primary contractual counterparty for that module.
- Sub-contractors and consortium partners must be disclosed at the proposal submission stage.
- The prime vendor is responsible for the performance of all sub-contractors and partners.
- Vendors may bid as prime on one module and as sub-contractor on another.
- AMA reserves the right to conduct due diligence on all named sub-contractors and partners.
- Material changes to consortium composition after ITR must be approved by AMA.

3.7 Submission Deadline and Format

Proposals must be submitted electronically by the deadline specified in Section 3.2. Late submissions will not be accepted under any circumstances. AMA procurement schedule will be the authoritative reference for submission timing.

Each proposal must be structured in accordance with the Response Format specified in Chapter 6 of this RFP. Each module response must break down the proposal by phase, and pricing must be presented as separate Phase 1 and Phase 2 schedules, as set out in Sections 6.2 and 6.6. Non-compliant proposals may be disqualified at the responsiveness screening stage (see Section 4.1). Proposals must be submitted in English. Supplementary materials in French, Portuguese, or Arabic (All AU languages are acceptable in the bidding) are permitted but must be accompanied by an English summary.

Refer to Chapter 6 for submission components and appendices.

3.8 Orals, Demonstrations, References, and BAFO

Select responding vendors will be invited to demonstrations and interviews; AMA's scored evaluation, which takes account of the demonstrations, follows them. Demonstration requirements will be shared with responding vendors ahead of scheduled demos. Sessions include:

- Oral presentations: Structured sessions in which vendors present their technical and commercial approach and respond to panel questions.

- System demonstrations: Live demonstrations against AMA-prescribed test scenarios, shared with responding vendors
- Reference checks: AMA will contact nominated reference customers to verify claims made in the proposal.
- Best and Final Offer (BAFO): If AMA determines that further commercial refinement is necessary, it may issue a BAFO request to one or more shortlisted vendors.

Vendors are expected to have senior technical and commercial representatives available for oral sessions. Misrepresentation of capabilities during demonstrations will be grounds for disqualification.

3.9 Award Process and Contracting Framework

AMA will award each module independently to the vendor (or consortium) that scores highest on the evaluation criteria described in Chapter 4, subject to meeting all mandatory minimum qualifications. AMA is not obligated to award every module, to the lowest-cost bidder, or to make any award at all.

AMA anticipates contracting on a module-by-module basis. Each awarded vendor will enter into a Master Services Agreement (MSA) with AMA, supplemented by module-specific Statements of Work (SoW) and Service Level Agreements (SLA). Contracts will be executed with AMA as the Client, with Garnet Partners Ltd joining in its capacity as Contract Management Partner and Fiscal Administrator. All contracts will be subject to AMA internal governance approvals, and to the grant and fiduciary policies administered by Garnet Partners Ltd.

Milestone payments under awarded contracts will be processed by Garnet Partners Ltd, only upon AMA's written acceptance of the relevant deliverables. Garnet verifies invoices and supporting documentation for financial accuracy but has no authority to accept deliverables on AMA's behalf.

AMA reserves the right to negotiate with one or more vendors prior to contract execution and to require adjustments to pricing, scope, or delivery plans as a condition of award.

3.10 Procurement Policies and Legal Terms

This RFP is issued by AMA through Garnet Partners Ltd and is subject to AMA internal governance approvals and the applicable grant and fiduciary policies administered by Garnet Partners Ltd. By submitting a proposal, vendors acknowledge and agree to the following:

- AMA is not liable for any costs incurred by vendors in the preparation of proposals.
- AMA reserves the right to amend, suspend, or cancel this procurement at any time without incurring liability.
- All information provided in proposals is subject to verification and will be treated as confidential.
- Vendors must declare any actual or potential conflicts of interest at the time of ITR submission.
- Any attempt to improperly influence the evaluation process will result in immediate disqualification and may be referred to relevant authorities.
- Awarded contracts will include provisions for data sovereignty, data residency within the African continent (or approved jurisdictions), GDPR-equivalent privacy protections, and cybersecurity standards commensurate with AMA risk posture.

The award will comprise per-phase statements of work. The Phase 1 (MVP) statement of work is effective on contract signature. The Phase 2 statement of work becomes effective only on AMA's issue of an Authorization to Proceed (ATP) following the MVP Stage-Gate described in Section 2.5.

AMA may defer the Authorization to Proceed for a defined period following the MVP Gate Review, during which the vendor's Phase 2 pricing is held firm in accordance with section 6.6, and may terminate the Phase 2 statement of work for convenience at the gate with liability limited to work properly performed and accepted under Phase 1.

No entitlement to Phase 2 mobilization, expenditure or margin arises before the Authorization to Proceed is issued. Phase 3+ scope described in this RFP is non-binding context and creates no commitment on AMA.

Chapter 4 - Selection Approach, Criteria and Minimum Requirements

This chapter defines how AMA will evaluate proposals. Prospective bidders must read this chapter in conjunction with Chapter 3 (process), and Chapter 5 (requirements). Proposals that do not satisfy the mandatory minimum qualifications described in Section 4.2 will not proceed to score evaluation.

4.1 Responsiveness and Eligibility

AMA will conduct an initial responsiveness check on all submitted proposals before commencing substantive evaluation. A proposal will be deemed non-responsive - and therefore ineligible for further consideration - if it:

- Is received after the submission deadline.
- Does not cover at least one complete module as specified in this RFP.
- Fails to include the mandatory qualification evidence specified in Section 4.2.
- Does not comply with the required response format (Chapter 6).
- Contains material misrepresentations or materially false information.
- Is submitted by a vendor that is subject to active debarment from any major procurement framework.
- Is submitted by a vendor that did not file an Intent to Respond by the specified deadline.

Responsiveness checks are pass/fail. A proposal that passes all responsiveness checks proceeds to the mandatory qualifications stage.

4.2 Mandatory Minimum Qualifications

AMA has established minimum qualification thresholds that a vendor must meet to be eligible for evaluation of any module. These are non-negotiable. A vendor that fails to demonstrate any single qualification will be excluded from all modules for which that qualification is relevant.

Vendors must provide supporting evidence for each qualification claim. Assertions without supporting documentation will not be accepted.

Qualification Area	Minimum Requirement
Legal standing	Vendor must be a legally registered entity in good standing with no active debarment from major procurement frameworks (AU, UN, World Bank, or equivalent).
Relevant sector experience	At least three (2) completed implementations in regulatory, health, or public-sector digital platforms, with at least one (1) serving a multi-country or regional user base.
eCTD / regulatory systems expertise	For Module 1 bidders: demonstrable experience in eCTD v4.0 platform deployment, including submission validation, reviewer workspace, and lifecycle management.
Data and integration capability	For Module 2 bidders: proven experience implementing MDM, IDMP-aligned data standards, or comparable regulatory master data programs.
Cloud and security baseline	For Module 3 bidders: ISO 27001 and ISO 27701 certification or equivalent; demonstrated deployment on a compliant cloud infrastructure (public, private, or hybrid).

Systems integration experience	For Module 4 bidders: documented experience as prime contractor or systems integrator orchestrating delivery across multiple technology vendors.
Financial capacity	Demonstrated financial viability through audited accounts or equivalent financial disclosure for the most recent two fiscal years.
Reference customers	Minimum two (2) reference customers (with work completed in the last 5 years) contactable by AMA during the evaluation process, at least one of which is in the health or medicines regulation sector.

4.3 Evaluation Dimensions and Weightings

Proposals that pass both the responsiveness check and the mandatory qualifications gate will be evaluated against the dimensions below. AMA will publish the precise scoring rubric and weighting coefficients separately. The evaluation dimensions listed below:

Category	Decision dimension	Description
Solution fit (~50%)	Functional fit	Does the solution fulfil the core functional requirements for AMA or NRAs? Does it address the MVP regulatory workflows?
	Technical fit	Alignment with AMA's planned target-state architecture and technical guiding principles. API compatibility, cloud readiness, and degree of customization required.
	Adoption fit	Availability of Hypercare and ongoing support. Vendor or AMA IT ability to maintain the solution. Clarity of change management and training plan.
	Feasibility fit	- Realistic timeline to have the solution live in early 2027. Considers procurement lead time, implementation, and African context fit. - Evaluation of vendor reputation, experience and provided references
Strategic fit (~20%)	Strategic alignment (current & future)	- Fit with AMA's 5-year digital strategy and North Star. Can AMA own and shape the end-state solution? - Is there committed future development that enables and accelerates AMA's vision?
Commercial fit (~30%)	Solution cost	Core software cost (license / subscription / development / maintenance). Ecosystem costs (third-party components, future customization to reach target state).
	Ecosystem cost	- Evaluation of cost associated with additional components required (e.g., 3rd party software) - Evaluation of future costs to align solution with AMA's digital target state (e.g., additional development / customization required)

Note on AI-readiness: AMA places particular emphasis on a vendor ability to integrate AI capabilities over time. Vendors should demonstrate how their solution architecture supports future AI-assisted review, automated validation, signal detection, and analytics. This is evaluated within the; Product Innovation; dimension above.

4.4 Component-by-Component Evaluation Approach

AMA will constitute a dedicated evaluation committee that will review submissions for each module. The evaluation committee may include:

- AMA technical staff with domain expertise relevant to the module.
- Representative(s) from the AMA Digitization Task Force (NRA ICT leads).
- Subject matter experts with relevant platform expertise.
- AMA procurement and legal representative(s).
- Representative(s) of Garnet Partners Ltd, participating in a procurement-administration and compliance capacity (non-scoring), consistent with Garnet's role as Contract Management Partner and Fiscal Administrator.

Sub-panels will score proposals independently. Cross-module coordination will be handled by the AMA Digital Lead to ensure consistency and to identify integration risks or synergies at module interfaces. The overall Digitization Task Force will be briefed on evaluation findings before final award decisions are taken, in line with AMA governance framework.

Three-Category Readiness Assessment

In addition to the scored evaluation dimensions, AMA will apply a readiness framework to determine whether shortlisted solutions can credibly support the early 2027 MVP launch. This framework assesses three categories:

1. **Functional Readiness:** Will the solution fulfil the outlined requirements and enable regulatory workflows as designed? Is AMA confident that the functional capabilities available will strengthen AMA institutional reputation and trust?
2. **Technical Readiness:** Will the solution scale into the outlined target-state system? Will AMA have the technical foundations (security, databases, networking) to support the solution as required?
3. **Adoption Readiness:** Is there a credible change management plan with outlined interventions to support user training and adoption? Will the solution have hyper-care support to address issues as they arise? Is there an IT service model to support digital solutions post-launch?

Chapter 5 - Solution Scope and Requirements

This chapter defines the functional and non-functional requirements for each of the five modules. For each module, AMA has specified: (a) the scope of activities to be delivered; (b) functional requirements; (c) non-functional requirements; and (d) vendor service obligations. Vendors must respond to each requirement individually using the Response Matrix templates in Appendix G.

The table below provides a high-level overview of all modules before the detailed specifications that follow.

Module	Name	Core Scope	Indicative Components
Module 1	eCTD	Electronic submission and reviewer workspace for dossier assessment	eCTD intake portal, AS4 gateway, validator, reviewer workspace, LoQ workflow, secretariat tools
Module 2	Data Standards & Integrations	Master data, terminology, and interoperability across regulatory systems	MDM / AMA-SPOR, IDMP alignment, ERP/billing integration, API gateway, HL7/FHIR standards
Module 3	Enterprise Setup	Identity, hosting, security, and productivity foundations	IAM/SSO, cloud infrastructure, SIEM, backup & DR, Microsoft 365 configuration
Module 4	Systems Integration	Multi-vendor orchestration, integration architecture, delivery governance	SI scope, sub-contractor model, NRA connectors, API layer, integration governance RACI
Module 5	RIMS Foundations	Regulatory Information Management; evaluated as optional scope	Submission portal, workflow engine, Market Authorization module, Clinical Trials module, lifecycle management

General Vendor Service Obligations

In addition to meeting the functional and non-functional requirements specified for each module, vendors are expected to fulfill a set of general service obligations applicable across the entire AMA Digital Platform.

These obligations define vendor responsibilities not only as a technology provider, but as a delivery and implementation partner operating within a multi-vendor, SI-led programme. The service obligations are captured in appendix C.

Vendors shall provide (see Service Obligation requirements in appendix):

- **End-to-end implementation** — Deliver end-to-end implementation services, including design, configuration, integration, testing, deployment, and support, aligned with AMA's phased roadmap (MVP and subsequent scale-up)
- **Design phase** — Complete a brief design phase, developing detailed architecture, integration, and operating model artefacts based on AMA's high-level strategy and principles
- **Multi-vendor collaboration** — Collaborate with other module vendors under the coordination of the Systems Integrator (SI), ensuring alignment of interfaces, data models, and integration patterns
- **Integrations** — Implement and validate all required integrations with internal AMA modules, external systems, and NRA environments, in accordance with defined interoperability standards
- **Testing** — Provide comprehensive testing, including functional, integration, performance, and security testing, ensuring readiness for production deployment

- **Regulatory validation** — Support regulatory validation and compliance requirements, where applicable, including provision of validation documentation and alignment with relevant standards
- **Documentation** — Deliver complete technical, functional, and operational documentation, including API specifications, configuration guides, and runbooks
- **Training & onboarding** — Provide training and onboarding support for AMA users and stakeholders, including train-the-trainer approaches and user adoption support
- **Knowledge transfer** — Ensure knowledge transfer to AMA teams to enable long-term sustainability, reduce vendor dependency, and support internal capability building
- **Post-deployment support** — Provide post-deployment support, including hyper-care, maintenance, incident management, and upgrades under defined service levels
- **Openness & portability** — Ensure solutions are designed and delivered with openness, interoperability, and portability in mind, including support for API-based access, data export, and future extensibility
- **Forward roadmap** — Develop a project plan for future developments in their respective component as outlined in the AMA strategy
- **Governance participation** — Operate within AMA's governance framework, including participation in program governance forums, risk and issue management, and adherence to defined RACI structures

These general obligations are complemented by module-specific vendor service obligations defined within each section of Chapter 5.

5.1 Capability / Component 1 - eCTD

AMA is looking to acquire a configurable, standards-based eCTD solution for document structuring, lifecycle management, validation, secure storage, and controlled access.

The eCTD is intended to be a back-end content and lifecycle management solution with a reviewer workspace to access the regulatory submissions: the Portal (5.5.2) and Workflow engine (5.5.3) sit outside it and integrate with it, and AMA may build / configure the reviewer workspace on top of the eCTD's services over time.

Beyond AMA's initial eCTD implementation, AMA is looking to support African NRAs in their eCTD development. AMA is requesting vendors submit a proposal for a multi-tenant / multi-user eCTD

The successful Module 1 vendor will be responsible for the following core activities:

- Deployment and configuration of an eCTD-compliant submission gateway for AMA that can be scaled to support the continent at latter phases.
- Integration with a secure industry portal to receive dossier and complete validation (AMA is open to hearing proposals for an integrated eCTD and submission portal)
- Implementation of an eCTD validation engine capable of checking submissions against ICH eCTD v4.0
- Deployment of a reviewer workspace enabling AMA rapporteurs, Technical Committee (TC) members, and secretariat staff to access, annotate, and assess dossiers.
- Configuration of structured LoQ (List of Questions) workflows including clock management and audit trails.
- Integration with AMA master data registry (Module 2) and enterprise identity system (Module 3).
- Training and change management for AMA staff and external applicants.
- Ongoing hypercare and system support through the MVP pilot period and into a steady state.

Phasing for this component.

Phase 1 (MVP): secure v4.0 (ICH M8) dossier intake, validation, receipt/storage/versioning/tracking, and sponsor-side authoring/publishing support. Also includes basic reviewer dossier access (potentially document creation)

Phase 2: advanced/automated validation and AI pre-screening. Improved usability

Context (Phase 3+): configuration of the eCTD for other regulatory processes and product types (e.g., Clinical trials, medical devices)

5.1.1 Scope of activities

The module provides an integrated environment combining submission intake and management, a reviewer and Secretariat surface, and the document/lifecycle services beneath them. Requirements are organized into eleven capability themes:

- **A.** Submission intake & Portal handover
- **B.** eCTD validation & initial report
- **C.** eCTD format & lifecycle management
- **D.** Dossier content repository / DMS
- **E.** Reviewer & Secretariat access surfaces
- **F.** LoQ & eCTD-linked correspondence
- **G.** Access control & identity enforcement
- **H.** Workflow & status integration
- **I.** Audit, traceability & reporting
- **J.** Reliance & NRA sharing readiness
- **K.** Open architecture & extensibility

Proposed submission journey:

- Sponsor completes the submission form and uploads the dossier on the AMA Sponsor Gateway
- The Portal hands the submission package to the eCTD.
- The eCTD validates against eCTD v4.0, the AMA Module 1 specification, and AMA business rules, and generates an initial validation report returned to the sponsor via the Portal.
- On acceptance, the dossier is stored in the eCTD DMS as the dossier-of-record.
- The Secretariat, and reviewers once assigned, access the dossier through the eCTD, governed by AMA's central access controls.
- The eCTD emits lifecycle events so the Workflow Engine can track progress, clocks, and milestones, and route work.

5.1.2 Functional requirements

68 functional requirements across the eleven capability themes (Fully detailed in Appendix C) Differentiated requirements are highlighted across the sections below.

Theme A - Submission intake & Portal handover

The eCTD receives submission packages handed over from the AMA Portal (5.5.2). It does not provide sponsor-facing submission channels itself. The eCTD owns the Portal-to-eCTD handover interface, and the integrity check on the received package.

Theme B - eCTD validation & initial report

Addresses validation of eCTD submissions against technical and regulatory criteria, including automated validation checks and generation of initial validation reports for submission acceptance or rejection.

Theme C - eCTD format & lifecycle management

Focuses on management of eCTD-compliant dossier structures, including sequence handling, lifecycle operations (e.g. replace, append, delete), and maintenance of compliant dossier evolution over time.

Theme D - Dossier content repository / DMS

Defines the storage and management of dossier content within a document management system, including structured storage, versioning, retrieval, and persistent linkage to regulatory workflows.

Theme E - Reviewer & Secretariat access surfaces

Covers user interfaces and workspaces for reviewers and AMA secretariat staff, enabling access to dossiers, annotations, collaborative review activities, and decision support.

Theme F - eCTD-linked correspondence

Includes management of regulatory correspondence such as List of Questions (LoQ), responses, and other interactions, ensuring structured linkage between communications and the corresponding eCTD dossier context.

Theme G - Access control & identity enforcement (eCTD-linked)

eCTD solution utilizes centrally defined role-based and federated access control mechanisms for dossier-related data, ensuring secure access aligned with user roles, regulatory responsibilities, and cross-organizational participation.

Theme H - Workflow & status integration

Covers integration with the workflow engine to manage submission status, process steps, clock management, and coordination of activities across multiple stakeholders and systems.

Theme I - Audit, traceability & reporting

Ensures full traceability of actions, changes, and decisions within the eCTD lifecycle, including audit logging, reporting capabilities, and support for regulatory compliance and oversight.

Theme J - Reliance & NRA sharing readiness

Addresses readiness for reliance-based workflows, including controlled sharing of dossiers and outputs with NRAs, support for distributed review models, and alignment with federated regulatory processes. The eCTD provides the sharing mechanism only; reliance policy, disclosure rules, and redaction requirements are defined in the regulatory modules (for example, Market Authorization, 5.5.4).

Theme K - Open architecture & extensibility

Defines requirements for an open, modular architecture, enabling extensibility, interoperability, and future integration with additional modules, systems, and external stakeholders.

5.1.3 Non-functional requirements

Vendors will be expected to adhere to the general the non-functional requirements in appendix E

5.1.4 Vendor service obligations

Unique vendor service obligations listed below the remaining ones are outlined in the functional requirements appendix (Appendix C)

5.1.5 Vendor response questions

Vendors responding to this module are asked to answer component specific questions in Appendix B

5.2 Component 2 - Data Foundations

Component 5.2 defines the data foundations layer of the AMA Digital Core, ensuring interoperable, standards-compliant, and scalable data exchange across all regulatory workflows and stakeholders.

This module is a critical enabler of AMA's regulatory operations. It supports data consistency, cross-border collaboration, and structured reuse of regulatory outputs while enabling a phased transition from an AMA-focused MVP to a broader continental platform.

Phasing for this component.

Phase 1 (MVP): foundational AMA-SPOR (Tier 0) sufficient to resolve entities at intake, audit trail, a SPOR read API, and lightweight validation/stewardship.

Phase 2: full IDMP enrichment, golden-record MDM, the data-governance operating model, NRA/ERP data integrations, and canonical cross-module IDs.

Context (Phase 3+): data products, analytics/AI, and continental federated data. See Section 2.5 for the canonical model.

5.2.1 Scope of activities

The Data Foundation module defines the data foundation layer of the AMA Digital Platform. It enables consistent, standards-based, and scalable data exchange across all regulatory workflows, modules, and stakeholders.

It is a foundational cross-module capability, supporting the federated AMA operating model and enabling data reuse, regulatory reliance, and cross-border collaboration.

AMA is looking for a vendor to support detailed design and development of AMA's outlined data foundations (see digital strategy for more detail) and implement solutions across the following areas:

Data architecture and foundation

- Establishment of a layered data architecture, including master data, transactional data, and analytical / insight layers
- Definition of data domains and ownership and data lifecycle management (creation, update, archival)

Master data and standards

- Implementation of AMA-SPOR as the authoritative master data capability
- Adoption of global regulatory data standards, including ISO IDMP and HL7 FHIR R5 where applicable

Analytics

- Design an analytical data layer, key reports and necessary integration in a repeatable manner
- Develop basic analytical dashboards based on data and transactions going through
- Outline requirements for AMA transactional data to enable streamlined analytics
- (future phase) Implement designed analytical layer pulling from regulatory and operational data

Data governance

- Definition of data governance structures, stewardship roles, data quality controls, and approval workflows
- Enforcement of data quality and data standards
- Enablement of reusable data products and analytics readiness for dashboards, reporting, and future AI-supported use cases

5.2.2 Conceptual data architecture

Conceptual data architecture – three logical zones



AMA's data architecture organized into three logical zones: Master data (slow-changing, authoritative), Transactional (high-volume operational), Analytical (read - optimized, derived). Strict separation maintained - analytical never reads operational DB.

MASTER DATA ZONE <i>Slow-changing , authoritative</i>	TRANSACTIONAL ZONE <i>High-volume , operational</i>	ANALYTICAL ZONE <i>Read - optimized , derived</i>
STORES - AMA-SPOR (4 services) - OMS , PMS , SMS , RMS - ISO IDMP compliant - FHIR R5 native	STORES - Submission Registry - Decision Log - Workflow state - Document Store (DMS) - Inspection Findings - Adverse Events	STORES - Submission Pipeline view - NRA Participation metrics - Performance dashboards - AI training corpus - BI / regulatory intelligence
EXCHANGE PATTERN <i>REST + FHIR R5 read-only for consumers. Write only via Operations team (registry-controlled).</i>	EXCHANGE PATTERN <i>Application-only access via REST. Pub-Sub events emitted on state changes. No direct DB queries from outside.</i>	EXCHANGE PATTERN <i>Read-only via OData / SQL view. DPO approval per dataset. Audit-logged. Time-bound credentials.</i>
TECH STACK COTS OOTB vs OpenSource	TECH STACK COTS OOTB	TECH STACK COTS OOTB

5.2.3 MDM / AMA-SPOR setup

The solution shall implement AMA-SPOR as the authoritative master data layer for the AMA Digital Platform. AMA-SPOR is intended to mirror the proven SPOR pattern used by leading regulators, while being adapted to AMA's African context, phased operating model, and federated collaboration approach.

AMA-SPOR is the shared reference-data capability that provides canonical identifiers, common data structures, and governed master records across the platform. It is not a standalone registry disconnected from operations. Instead, it is progressively populated and enriched through sponsor submissions, regulatory workflows, trusted continental assets, and selected external reference sources.

At minimum, the solution shall support the following four master data domains:

Four services overview - OMS, PMS, SMS, RMS at a glance



Each service is a master data domain with its own steward, ISO standard, FHIR resource, identifier convention, and Phase 0 minimum viable scope.

OMS Organisation Management Service	PMS Product Management Service	SMS Substance Management Service	RMS Referentials Management Service
ISO STANDARD ISO 11615 (org block)	ISO STANDARD ISO 11615 + 11616	ISO STANDARD ISO 11238	ISO STANDARD ISO 11239 + 11240
FHIR RESOURCE Organization	FHIR RESOURCE Medicinal Product Definition	FHIR RESOURCE Substance Definition	FHIR RESOURCE Code System / Value Set / Concept Map
IDENTIFIER AMA-orgID (UUID)	IDENTIFIER AMA-productID (UUID)	IDENTIFIER AMA-substanceID (UUID)	IDENTIFIER Per-vocabulary URIs
PHASE 0 SCOPE Org ID, name, type, address, country, DUNS, status	PHASE 0 SCOPE Product ID, INN, dose form, strength, route, ATC, MAH, status	PHASE 0 SCOPE Substance ID, INN, CAS, UNII, type, status	PHASE 0 SCOPE Adopt: WHO ATC, WHO INN, MedDRA, EDQM, ICH M8 CV, Publish: AMA procedure types, decision codes
SCALE ~2,000 orgs (Y1) → 10,000+ (Y5)	SCALE 100 products (Y1) → 5,000+ (Y5)	SCALE ~500 substances (Y1) → 5,000+ (Y5)	SCALE 200+ vocabularies (mix of adopted + AMA-owned)
STEWARD Operations Director	STEWARD Pre-Authorisation Unit Lead	STEWARD Vigilance & MS Unit Lead	STEWARD QMS / Data team
PRIMARY CONSUMERS All transactional systems, IAM federation, NRA Portal	PRIMARY CONSUMERS Reviewer Workspace, Sponsor Portal, NRA Portal, Afrivigilance, Public Register	PRIMARY CONSUMERS PMS, Reviewer Workspace, Afrivigilance, NRA Portal	PRIMARY CONSUMERS All systems requiring controlled vocabulary lookup

The solution shall also support workflow-based approval for master data changes, including submission, review, approval / rejection, versioning, and full audit trail of all changes to governed reference data.

Detailed information is available in AMA's strategy.

5.2.4 Other MVP data foundations

The solution shall include core data capabilities required for MVP and future scaling.

Integration core components

The solution shall connect with integrations established in the enterprise foundations chapter including:

- API Gateway (centralized entry point for all integrations)
- Event-driven integration layer (event mesh)
- File-based integration (for low-maturity NRAs)

Data products and services

The solution shall support:

- Definition of reusable data products
- API exposure of structured data
- Cross-module data sharing using canonical identifiers

The table below outlines 12 initial data products outlined in the AMA strategy as being a priority for initial development:

#	Data Product	Owner	Output Format	Primary Consumers	Tier
1	Product Registry (PMS Phase 0)	Pre-Auth Unit	FHIR R5 + REST	Reviewer Ws , Sponsor Portal, NRA Portal, Public Register	SPOR
2	Organisation Registry (OMS)	Operations + Pre-Auth	FHIR R5 + REST	All transactional systems, IAM federation	SPOR
3	Substance Registry (SMS Phase 0)	Vigilance & MS Unit	FHIR R5 + REST	PMS, Reviewer Ws , Vigilance, NRA Portal	SPOR
4	RMS Controlled Vocabularies	Quality + Data team	REST (cached)	All systems requiring lookup	SPOR
5	Assessor Registry	Quality + HR	REST + OData	Workflow Engine (rapporteur assignment)	Source-aligned
6	Sponsor / Submitter Registry	Operations	REST + FHIR	Sponsor Portal, Submission Portal, OMS	Source-aligned
7	Decision Log (immutable)	Pre-Auth + Quality	Append-only event store	NRA Portal, Public Register, Audit, ERP	Source-aligned
8	Audit Trail	Quality	Time-series store	QMS, regulatory inspections, WLA submission	Source-aligned
9	eCTD Sequence Manifest	Operations	XML (RPS R2) + REST	DMS, Reviewer Ws , validation engine	Source-aligned
10	Inspection Findings	Inspections team	REST	Reviewer Ws , Manufacturer profile, NRAs	Source-aligned
11	Submission Pipeline (analytical)	Operations	OData / SQL view	Service Dashboard, DG Dashboard	Derived
12	NRA Participation metrics	Partnerships + Ops	OData / dashboard	Performance Dashboard, DG, Partnerships	Derived

5.2.5 Functional and non-functional requirements

Functional Requirements

Theme A - Master Data Management (AMA-SPOR)

Defines the management of core regulatory master data domains (AMA-SPOR), including creation, maintenance, and governance of reference data for products, substances, organizations, and related entities across regulatory workflows.

Theme B - Data Governance and Quality

Covers establishment of data governance frameworks, including roles, processes, and controls to ensure data quality, consistency, integrity, and compliance across the AMA ecosystem.

Theme C - Event-driven architecture

Focuses on enabling event-driven data exchange and system interaction, supporting real-time or near real-time communication across systems through events, messaging, and asynchronous processing patterns.

Theme D – External integrations

Covers data integrations with external systems and stakeholders, including NRAs, third-party platforms, and enterprise systems, enabling secure, standards-based data exchange and interoperability across the AMA regulatory ecosystem.

Theme E – Data products and analytics readiness

Focuses on preparation of data for reporting, analytics, and AI use cases, including the structuring of data products, support for dashboards and performance monitoring, and enablement of advanced analytics across regulatory processes.

Non-Functional Requirements

Unique vendor service obligations listed below. Additional service obligations are provided in appendix C and in the functional requirements appendix (Appendix C) **5.2.6 Vendor delivery expectations and design phase scope**

Context

AMA has defined the high-level vision including architectural principles, target data domains (e.g. AMA-SPOR), and interoperability concepts. The detailed solution design has not yet been developed. The vendor will be expected to **lead and deliver the detailed design**, then build, integrate, and deploy the module in alignment with AMA's defined vision and requirements.

1. Delivery approach and plan

The vendor's proposal must include:

- An end-to-end delivery approach aligned to AMA's phased roadmap (Phase 1 (MVP) → Phase 2 → Phase 3+ (context)), with timelines for each design artefact
- A project plan covering design, build & configuration, integration & testing, and deployment & rollout
- Dependencies, assumptions, and risks for data architecture and integration
- A clear split of all activities into **Phase 1 (MVP)**, Phase 2, and **Phase 3+ (context only)**.

Phase boundary. At Phase 1 (MVP), AMA-SPOR is deliberately minimal ("SPOR Tier 0" in AMA's digital strategy): the four services are stood up with only the fields needed to identify and resolve the organizations, substances, products and referentials on an incoming submission, seeded by reference from authoritative sources (WHO INN, EMA/ICH terminologies) and the AMRH API Database, and exposed via HL7 FHIR R5.

The vendor proposes the exact MVP data domains during design. Governance at MVP is limited to the stewardship, validation, and audit needed to keep this record reliable. The vendor also delivers, as design artefacts, the data-architecture blueprint, master-data model and a SPOR development roadmap that defines, but does not build, the Phase 2 scale-up. Full IDMP enrichment, the data-governance operating model, golden-record MDM, the enterprise API gateway and event mesh, NRA registry synchronization, and the master-data intake/front-end views are Phase 2.

2. Design deliverables

The vendor produces or validates the following:

- **Data architecture blueprint** — logical and physical architecture; data layers and data flows
- **Master data model (AMA-SPOR)** — entities and relationships for each SPOR element; standardised structures and identifiers; a SPOR development roadmap; and the MVP electronic Application Form (eAF) for Market Authorization, Sponsor Registration, and inspections
- **Data governance operating model** — roles (data owners, stewards); data quality and validation processes; governance workflows
- **Integration architecture** — integration patterns (API, event-driven, file-based); API design principles and interface specifications; event and message model
- **External integration model** — NRA integration by maturity level; Member State onboarding playbook; approach for external systems (ERP, PV)
- **Data exchange & interoperability specifications** — exchange formats and standards; alignment with international standards (IDMP, FHIR where applicable)

Scope area	Inputs from AMA	Expected vendor deliverables	Phase
Master Data (AMA-SPOR)	High-level domains and definitions	Detailed data model, entity definitions, governance model	Design
Data governance	Initial principles	Governance framework, roles, workflows, data quality rules	Design
Integration layer	Target architecture concepts	Integration patterns, API specifications, event model	Design
NRA integration	Federated model concept	NRA integration approach, maturity model, onboarding plan	Design + Build
External integrations (e.g., ERP)	Integration requirements	Interface design, data mapping, integration workflows	Build
Data exchange standards	High-level direction	Data formats, exchange protocols, interoperability definitions	Design

5.2.7 Vendor response questions

Vendors responding to this module are asked to address questions in Appendix B.

5.3 Capability / Component 3 - Enterprise Setup

Module 3 defines the foundational enterprise IT capabilities required to operate the AMA Digital Platform, including cloud infrastructure, cybersecurity, enterprise productivity, and IT service operations. It translates the AMA Digital Strategy into the enterprise foundation that all regulatory and shared platform components will consume rather than rebuild.

Across the strategy work completed for AMA, enterprise setup is consistently treated as part of the AMA Digital Core rather than as a stand-alone back-office topic. The cloud foundation, service management, compliance and cybersecurity capabilities are the common layer that enables reliable operation of the market-authorization platform, reviewer workspace, data foundations, integrations, and future modules.

Phasing for this component.

Phase 1 (MVP): AU-resident cloud landing zone, backup/restore, IAM/SSO with RBAC and MFA, encryption, centralized audit logging, basic operational monitoring and incident handling, and identity/security-adjacent M365.

Phase 2: full DR, SIEM/SOC/CSPM and DLP, the ITSM platform with CAB/SLA/problem management/CMDB, and the productivity roll-out.

Context (Phase 3+): cyber L3/L4 (Zero Trust, threat hunting), full ITIL 4 / ISO 20000, and multi-tenant activation. See Section 2.5 for the canonical model.

5.3.1 Scope of activities

The Enterprise Setup module defines the target operating environment and the shared enterprise capabilities required to support the AMA Digital Platform from MVP through continental scale-up.

AMA is looking for a coordinating vendor to procure, implement and integrate the set of solutions listed below in this section. The vendor will be expected to propose specific solutions aligned with AMA's strategy and requirements.

In scope, the module includes:

- **Cloud hosting and infrastructure:** Cloud landing zone, compute and storage services, network architecture, backup and disaster recovery, and environment management (dev/test/prod)
- **Cybersecurity and identity:** Identity and access management (IAM), encryption, security monitoring (SIEM/CSPM), data protection controls, and compliance mechanisms aligned with AMA requirements
- **Enterprise productivity and user environment:** Integration with enterprise collaboration tools (e.g., Microsoft 365 or equivalent), user workspaces, notifications, and role-based user views
- **IT service management (ITSM):** Tools and processes for incident management, change management, service requests, monitoring, and operational support
- **Cross-cutting enterprise capabilities:** Logging, monitoring and auditability

5.3.2 Cloud storage and infrastructure

The solution shall adopt a cloud-first, sovereign-by-design approach to hosting the AMA Digital Platform. AMA's cloud strategy defines how the platform is hosted, scaled, and secured across the African continent, covering IaaS, PaaS, and SaaS layers, while aligning with AU data governance frameworks and member-state sovereignty expectations.

The target cloud model shall support the following strategic principles:

- Sensitive and regulatory data shall remain within Africa-resident cloud infrastructure.
- The architecture shall scale from the initial EOI/MVP scope to wider deployment across up to 55 NRAs without re-platforming.
- Preference shall be given to managed services to reduce infrastructure overhead for AMA's lean internal team.
- The environment shall enforce identity management, encryption, centralized audit logging, and network segmentation from Phase 1 (MVP). Continuous security monitoring (SIEM/CSPM) is established in Phase 2.
- The architecture shall avoid lock-in to a single provider through use of API gateway patterns and modular service design.
- Cloud-first, sovereign-by-design architecture, with regulatory data hosted within Africa and no dependency on new on-premise infrastructure
- Resilient and scalable deployment model, including multi-region support, high availability, backup, and disaster recovery aligned with defined recovery objectives
- Ability to support distributed operations across geographies, ensuring continuity of service and alignment with AMA's federated operating model

Cloud governance shall reflect the strategy decisions taken during the project: a central Cloud Centre of Excellence sets standards, security posture, and cost governance, while domain teams own service-level deployment within those standards. All cloud services should be accessed through a central API gateway to ensure consistent security, observability, and portability.

Indicative storage and usage estimates:

Data category	Description	Estimated volume (initial)	Growth expectation	Access pattern
eCTD dossiers	Submission files and documents	High (TB-scale)	Increasing with submissions	Read-heavy (review phase)
Regulatory data	Structured application and workflow data	Medium	Gradual growth	Mixed read/write
System logs	Audit logs and system monitoring data	Medium	High growth	Write-heavy
Analytics data	Reporting and analytics outputs	Medium	Increasing	Read-heavy
User-generated content	Notes, annotations, communications	Low–Medium	Increasing	Mixed

Vendors shall validate and refine these estimates and propose an appropriate storage, resilience, and cost model based on their solution. Some solutions (e.g., eCTD) may provide their own cloud storage solutions.

Disaster recovery and business continuity

The solution shall include a comprehensive Disaster Recovery (DR) and Business Continuity approach to ensure the resilience of AMA's cloud-based platform including failover to a disaster recovery environment in the event of service disruption, restoration of services with minimal data loss, and continuity of critical regulatory operations

The DR approach shall include:

- Definition of a Disaster Recovery architecture, including primary and secondary (DR) environments
- Geographic separation of deployment regions where feasible

- Data backup and recovery mechanisms
- Defined recovery objectives, including Recovery Time Objective (RTO) and Recovery Point Objective (RPO)
- Procedures for restoring platform services and validating data integrity following a disaster or significant service disruption.

5.3.3 Cybersecurity and privacy

The solution shall implement a comprehensive cybersecurity and privacy architecture aligned with AMA's regulatory obligations and continental operating context. The strategy materials define cybersecurity as a full control framework.

The cybersecurity model shall be based on the following strategic principles:

- Zero Trust security-by-design is the preferred model for AMA's cloud-native, multi-tenant architecture.
- The security framework shall align with AU cybersecurity requirements, GDPR-equivalent data protection principles, and international frameworks such as NIST CSF and ISO 27001.
- Data classification shall be mandatory, with differentiated controls for PUBLIC, INTERNAL, CONFIDENTIAL, and RESTRICTED data.
- RESTRICTED data shall remain in Africa-resident infrastructure and use strong encryption with customer-managed keys for the most sensitive tier.
- At Phase 1 (MVP), the solution shall deliver SIEM tooling, centralized audit logging and the core identity and encryption controls, together with defined incident-response obligations. The 24/7 SOC operating model, cloud security posture management (CSPM) and tuned data-loss prevention are established in Phase 2. The audit trail is required from Phase 1 (MVP).

Identity and access model

- Centralized identity and access management shall be used across all systems.
- The solution shall support SSO, MFA, RBAC, and ABAC where needed.
- No standing privileged access should be assumed for sensitive workloads; least-privilege principles shall apply.
- The model shall support federated participation by different user groups without weakening central policy enforcement.

Because AMA's workflows require tightly controlled participation of reviewers, assessors, and other actors, the enterprise security model should support case-aware, assignment-driven access to sensitive content. Further details on AMA's security strategy can be found in the digital strategy.

Control area	Strategy direction	What vendors should address in their proposal
Zero Trust access	MFA, RBAC/ABAC, JIT-style privileged control, no implicit trust	Explain how access is enforced across cloud services, applications, and collaboration tooling
Encryption	AES-256 at rest and TLS 1.3 in transit; stronger key custody for RESTRICTED data	Explain encryption design, key management, and how restricted data is isolated and protected
Monitoring and response	Phase 1 (MVP): SIEM tooling, centralized audit logging and incident handling. Phase 2: 24/7 SOC operating model, CSPM and tuned DLP	Explain threat detection, alerting, log retention, response model, and SI/SOC responsibilities
Data sovereignty and privacy	Africa-resident handling for restricted data; DLP / exfiltration controls; AU / privacy alignment	Explain regional hosting, exfiltration controls, and privacy-by-design controls

Vendor and third-party controls	Security assessment obligations and breach governance	Explain vendor-assurance model, third-party access restrictions, and security onboarding expectations
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5.3.4 Productivity (M365 and user view configuration)

The solution shall support enterprise productivity and collaboration capabilities that enable AMA staff and other authorized users to work effectively across a distributed, cross-border operating model. The solution should therefore support the following productivity and user-experience principles:

- Integration with Microsoft 365 or equivalent enterprise productivity tools for email, calendar, collaboration, and document-related workflows
- Consistent identity and sign-on experience across enterprise productivity tools and platform components
- Role-based user views and dashboards for key user groups, aligned with responsibilities and access rules
- Support for document-centric collaboration, notifications, and audit-friendly working practices
- Configuration of user-facing experiences as part of the enterprise setup rather than bespoke rebuilding of commodity tools

Indicative user group	Expected productivity / view requirement	Recommended implementation stance
AMA internal users	access to enterprise productivity tools, notifications, document collaboration, and role-based dashboards	configure M365 / SaaS capabilities and integrate with central IAM and platform workflows
NRA participants and assessors	controlled user access, shared views where explicitly allowed, and secure collaboration on assigned work	expose only the views and collaboration surfaces required by role, policy, and workflow participation
External stakeholders / sponsors	use of dedicated external-facing channels rather than access to internal productivity spaces	separate external channel design; do not expose internal productivity environment by default

5.3.5 IT Service Management (ITSM)

The solution shall support an IT service management model that reflects the regulatory criticality of AMA's platform and the fact that the institution will start with limited internal capacity. The ITSM strategy prepared during the project defines ITSM as the operating model through which AMA turns digital services into reliable, measurable, and governable services, rather than as a generic service desk layer.

The ITSM target state shall support:

ITSM area	Strategy direction	Initial timing	Why it matters for the RFP
Incident management	Structured logging, triage, severity levels, escalation, and response governance	Phase 1 (MVP), basic (lightweight, SI-run during hypercare)	Needed to protect NRA trust and respond quickly to critical operational issues
Change management	Formal approval and control of production changes through governance (e.g., CAB)	Phase 1 (MVP), basic (lightweight); formal CAB and full ITSM platform: Phase 2	Prevents unauthorised changes that could disrupt regulatory operations or corrupt data

Service requests	Structured user request handling and fulfilment for access, support, and configuration matters	Phase 1 (MVP), basic (lightweight, likely SI-run during hypercare)	Provides operational discipline for distributed users and stakeholders
Problem management + CMDB	Root-cause management and controlled view of configuration items / dependencies	Phase 2	Improves impact assessment, resilience, and trend-based service improvement
Service dashboards and SLA reporting	Visibility into uptime, incidents, resolution times, and service quality	Phase 1 (MVP), basic dashboards; full SLA framework: Phase 2	Allows AMA to evidence reliability to leadership, partners, and future accreditation stakeholders
System monitoring and Evaluation	Single monitoring layer across system health, security, service consumption and data quality, with defined metrics and reporting cadence	Phase 1 (MVP), health, integration and audit-trail monitoring; wider security, FinOps and data-quality monitoring: Phase 2	Gives AMA one evidence base for availability, security, cost and regulatory performance

System monitoring and evaluation (M&E) is the always-on view of platform and service performance across four layers: system health, security and access assurance, service management and consumption, and business and data quality. Vendors shall state which monitoring types they provide natively, and how outputs are consolidated into a single view for AMA.

5.3.6 Functional and non-functional requirements

Functional Requirements (differentiated requirements listed below – full requirements in Appendix C)

Theme A – Cloud infrastructure and hosting

This theme covers the cloud hosting environment underpinning the AMA platform, including region selection, tenancy, resilience and scalability. Requirements address how compute, storage and network services are provisioned and managed in line with AMA's data sovereignty expectations.

Theme B – Identity and access management (IAM)

This theme covers how users across AMA, NRAs and industry are authenticated and authorized, including federated identity, single sign-on and role- and attribute-based access. Requirements ensure consistent, auditable access control across all platform components.

Theme C – Cybersecurity and monitoring

This theme covers protective and detective security controls across the platform, including continuous monitoring of system and user activity, threat detection and incident escalation. Requirements support early identification and response to security events affecting regulatory operations.

Theme D – Data protection and compliance

This theme covers safeguards for regulatory and personal data, including encryption, retention, data residency and complete audit trails of system actions. Requirements support AMA's compliance obligations and the evidentiary standards expected of a regulatory platform.

Theme E – Productivity and collaboration

This theme covers the everyday tools AMA staff and partners use to work together, including document collaboration, messaging, meetings and shared workspaces. Requirements address secure collaboration across distributed teams and Member State stakeholders.

Theme F – IT operations and service management

This theme covers the operational disciplines that keep the platform running, including health monitoring and alerting, incident and change management, and service request handling. Requirements align to the service management capabilities and phasing set out earlier in this section.

Vendor service obligations

Service obligations outlined in appendix C.

5.3.7 Vendor delivery expectations and design phase scope

Vendor delivery expectations and implementation approach

In addition to meeting the functional and non-functional requirements outlined in this section, vendors are expected to propose a comprehensive approach to the design, implementation, and operation of the Enterprise Setup module.

Vendors shall provide:

- A detailed implementation and deployment approach covering cloud infrastructure, security, identity, and productivity services
- A project plan covering:
 - design phase
 - configuration and build
 - testing and validation
 - deployment and rollout
- Identification of key dependencies, assumptions, and risks related to infrastructure, security, and enterprise services

The proposed approach shall clearly distinguish between MVP and subsequent phases.

Given that AMA has defined high-level principles for cloud, security, and enterprise setup, but does not yet have a fully detailed enterprise architecture design, vendors are expected to lead the design phase.

The vendor shall deliver:

- **Finalized cloud architecture blueprint**
 - hosting model, region strategy, and data residency approach
 - high availability and disaster recovery architecture
- **Identity and Access Management (IAM) design**
 - user identity model across all stakeholders (AMA and NRAs)
 - Detailed role-based and federated access approach
 - Coordinated plan with SI to implement IAM across AMA systems
- **Cybersecurity architecture**
 - security controls, monitoring, and incident response model
 - compliance with applicable standards
 - Coordinated plan with SI to implement cybersecurity across AMA systems
- **Environment and deployment model**
 - separation of environments (dev/test/prod)
 - deployment and release processes
- **Service model design**
 - Definition of the target service operating model for AMA's digital platform, including roles and responsibilities across AMA, System Integrator (SI), and module vendors
 - Service support model, including incident management, change management, and escalation processes aligned with ITSM practices
 - Definition of SLA framework for availability, performance, and support services

- Transition and knowledge transfer approach from vendor-led operations to AMA-managed or hybrid service model over time
- **Productivity and collaboration integration design**
 - integration with tools such as M365 or equivalent
 - user experience and workspace mode

Current state and expected vendor contribution

AMA has defined high-level principles for cloud-first deployment, security, and enterprise capabilities. However, detailed design decisions related to infrastructure architecture, IAM, security implementation, and operations are yet to be finalized.

Vendors are therefore expected to:

- Refine and operationalize the enterprise setup design
- Translate high-level principles into detailed, implementable architecture (with clear documentation for future handovers)
- Propose scalable and secure solutions aligned with AMA's digital strategy and federated needs

5.3.8 Vendor response questions

Vendors responding to this module are asked to address questions in Appendix B.

5.4 Component 4 - Systems Integration

Phasing for this component.

Phase 0: Discovery (outlined below in this section)

Phase 1 (MVP): the integration-platform baseline plus the internal MVP integrations (eCTD gateway to validation to workflow/DMS to reviewer workspace; portal to gateway to notifications; IAM/SSO to user-facing platforms; SPOR resolution).

Phase 2: API gateway and event mesh in production, AfriVigilance E2B(R3), ERP/billing, AMA-SPOR to all-modules sync, initial NRA (ML3) integrations, and eCRES/expert-management integration.

Context (Phase 3+): continental NRA/REC and global partner integrations, and legacy migration. See Section 2.5.

5.4.1 Role, ways of working & partnership principles

AMA's digital platform is built around a Digital Core with integration and interoperability at its center: AMA's digital components deliver their value only as a connected ecosystem rather than isolated applications. Module 4 governs the integration fabric that binds these together and extends AMA's digital reach across the continental regulatory community. The Systems Integrator (SI) is therefore both a technical implementer and a strategic interoperability enabler.

As previously outlined, AMA expects the Systems Integrator to directly bid or sub-contract for the Data Foundations and Enterprise Foundations components of this RFP. The Systems Integrator may also bid or sub-contract for the remaining components if they choose.

AMA contracts each module independently; the SI is accountable for the integrated solution working end to end — not only for its own scope. This accountability extends to end-to-end process performance across the workflow engine and the portals, even where those components are delivered by other vendors. In all cases, the SI may not subcontract the irreducible core — the integration architecture, the orchestration logic, and end-to-end integration testing and acceptance. AMA retains ownership of business goals, compliance, and budget.

AMA seeks a collaborative delivery partnership rather than a transactional supplier relationship. This module is framed around outcomes, deliverables and ways of working, and is evaluated on the SI's

demonstrated capacity and its governance model for multi-vendor orchestration (Chapter 4) — not a feature-compliance matrix. AMA expects the SI to:

- **Act in AMA's interest — providing** independent assurance and neutralizing individual vendor motivations.
- **Surface risk early and transparently — rather** than waiting for escalation.
- **Codify and transfer knowledge — building** AMA's internal capability through reusable patterns and codified knowledge, recognising AMA's intent to retain a majority-internal team and, over time, to advise NRA ICT teams across the continent.
- **Coordinate all parties to a single integrated outcome — with** one accountable delivery view.

5.4.2 Scope of activities

The SI's scope spans the integration platform and the connections across modules and external systems, delivered in phases. Two scope principles frame it:

- **Build boundary — the** SI integrates, deploys, coordinates and operates the components that the application module vendors build (eCTD, Portal/RIMS and Workflow); it plan-and-builds the integration layer — iPaaS, API gateway and event mesh — and supports the integration of existing systems AMRH API database and ECRES expert management system.
- **Foundation accountability — the** SI is contractually accountable for the Data (Module 2) and Enterprise (Module 3, including IAM, hosting and security) foundations, which it must build or subcontract. The SI proposes its own subcontractors and remains the single point of accountability; AMA may receive dedicated submissions for these modules and nominate a subcontractor only in exceptional cases (see 5.4.5).

AMA expects SI vendors to propose a cost-estimated discovery and implementation plan with milestones, outcomes, and stage gates. Below is an outline of the phases AMA is expecting vendors to structure their proposals around:

Discovery (Phase 0).

A short, time-boxed phase that validates scope, confirms the integration inventory and source-system readiness (including AMRH API database, ECRES expert management system and), produces the integrated project plan and a baseline RAID, and solidifies the SI's implementation plans, so the larger delivery commitment is confirmed after discovery rather than estimated before it.

Phase 1 (MVP) / first go-live (early 2027; first continental listing).

Establish the integration platform and deliver the internal system-to-system integrations and the AMRH API database integration. Potential initial integrations include:

- eCTD submission gateway → validation engine → workflow & case management.
- Workflow management → document management (DMS) → reviewer workspace.
- Applicant portal → eCTD gateway → correspondence & notification.
- IAM / SSO → all user-facing platforms; and analytics / BI → operational data sources.
- Full set of integrations to be defined by AMA and validated by SI vendor during discovery

Phase 2 — Foundations & Market Authorization (2027).

Bring the enterprise integration platform into production and deliver the external and cross-module integrations that support the full Market Authorization capability:

- API gateway and event mesh in production.
- AfriVigilance (HaloPV) integration, E2B(R3).
- ERP (financial management) → applicant portal (fee billing, payment confirmation, receipts).
- AMA-SPOR master data → all regulatory modules (product, substance, organization, referential sync).

- Initial NRA integrations at maturity level 3 (ML3).
- eCRES / expert management integration.

Phase 3+ — continental & global (context). Roadmap-only, not priced in this engagement; described for context.

These extend AMA's reach across the continental community and will be commissioned in later phases:

- NRA & REC connectivity — a standardized, maturity-tiered NRA Integration Kit (file-based exchange for ML1–2; real-time APIs for ML3–4) and integration with AMRH-linked RECs (e.g., ZAZIBONA/SADC, ECOWAS/WAHO, EAC), including RISP-compatible data exchange.
- Global partner integrations — WHO VigiFlow/VigiBase, EMA SPOR, AfriVigilance (AU-3S), and future ICH / IPRP gateways.
- Continental legacy migration — onboarding structured data from predecessor systems (e.g., ZAZIBONA RISP, legacy NeeS) into AMA's canonical data model.

5.4.3 Functional requirements

The requirements in appendix C apply to the integration platform and layer the SI builds. For each, vendors indicate in the response matrix whether it is met out-of-the-box, by configuration, or by custom development, with indicative effort.

5.4.4 Non-functional requirements & service levels

These define the quality, performance, security and operational standards for the integration platform and the SI's delivery and form the basis of the run-phase service levels. Vendors state the proposed platform product(s) and version(s), evidence of compliance from comparable deployments, and proposed SLA terms including remedies for material breaches.

5.4.5 Program Delivery Outcomes & deliverables

The SI is accountable for: an integrated platform delivered to the outlined scope and accepted by AMA; an on-time, on-budget MVP go-live in early 2027; passed system-integration, user-acceptance, performance and security testing; a secure and sovereign solution (data residency on the African continent and GDPR-equivalent privacy protections); adoption by AMA staff and external applicants; reusable integration patterns and codified knowledge transferred to AMA; and stable operations to agreed service levels, including hypercare.

Key deliverables.

Deliverable	Outcome / description	Cadence / timing	Acceptance
Discovery report & firmed estimate	Validated scope, confirmed integration inventory and source-system readiness (incl. AMRH, ECRESS), refined plan and baselined RAID, and a firmed 2027 estimate.	End of discovery (Phase 0)	AMA gate sign-off
Integrated solution architecture & design	End-to-end architecture across all modules and the integration layer.	Early build; baselined	Design authority approval
Integrated project & delivery plan	A single plan across all module vendors (partnered or independent), with milestones, dependencies, governance and resourcing.	Baselined after discovery; maintained	Steering committee approval

Deliverable	Outcome / description	Cadence / timing	Acceptance
Integration platform & layer	The iPaaS, API gateway and event mesh built and operated by the SI.	Per plan	Meets SI-FR / SI-NFR; SIT pass
Data & Enterprise foundations	The Data and Enterprise foundations delivered (built or subcontracted by the SI) and integrated.	Per plan	Per module acceptance; integrated
Integration pattern library	Reusable integration patterns and templates, lowering the cost and risk of future integrations.	Established early; maintained	Documented, applied and accepted
RAID log & change register	Living registers of risks, assumptions, issues, cross-vendor dependencies and governed changes.	Maintained; reviewed bi-weekly	Current at each steering committee
Interface control register	All cross-module interfaces, their owners and contracts.	Maintained	Basis for integration testing
Integration build (incl. AMRH, ECRESS)	Built and tested integrations across the 2027 scope, including the ad-hoc source integrations.	Per plan	SIT pass
Test strategy & results	End-to-end evidence across SIT, UAT, performance and security testing.	Per quality gates	Gate exit criteria met
Change management, training & onboarding	Adoption by AMA staff and external applicants; readiness for launch.	Through delivery; at launch	Adoption / readiness criteria met
Deployment, cutover & go-live	Production deployment and cutover to live operation.	Go-live milestone	Go-live acceptance criteria met
Knowledge codification & capability transfer	Codified architecture decisions, standards, runbooks and reusable assets transferred to AMA.	Ongoing; at transition	AMA acceptance; repository handover
Operational reporting	Weekly integration status (active delivery); monthly integration health dashboard (from go-live).	Weekly / monthly	Delivered each cycle
Managed services, hypercare & run	Operate, support and maintain the platform to agreed service levels, including post-launch hypercare.	Post go-live, ongoing	SLA attainment

Service-level targets are defined in 5.4.4 and confirmed during discovery; acceptance / quality gates between phases govern milestone payments.

5.4.6 Delivery & governance model

- **Delivery & coordination model** — AMA awards and contracts each module independently. Vendors may bid alone, as a consortium, or as prime/sub. The SI is the coordinating delivery partner accountable for integration across all modules and must coordinate both vendors partnered with it and vendors contracted independently by AMA — maintaining single-point integration accountability and clear interface ownership in each case.
- **Foundation subcontracting** — The SI proposes its own subcontractors for the Data and Enterprise foundations modules (5.2 and 5.3) and remains the single point of accountability. AMA may nominate a subcontractor only in exceptional cases — for example, where a compelling standalone specialist bid is received — subject to the SI's reasonable due diligence and a management fee on nominated-subcontractor scope.
- **Cooperation obligations** — AMA will require all module vendors, through their agreements, to cooperate with the SI's integration process — conforming to interface specifications and participating in integrated testing and the delivery cadence.
- **Governance ownership** — The SI proposes and owns the delivery governance and operating model; AMA reviews and provides feedback. SI's are expected to propose a governance model the aligns to the anchors and workstreams outlined below
- **Fixed anchors (set by AMA)** — The AMA Project Steering Committee (senior AMA leadership) is the decision and escalation body, to which the SI reports bi-weekly; AMA provides a focal point / owner for each workstream; AMA holds defined decision rights; a weekly operational cross-vendor cadence is run by the SI. The SI will propose additional governance structures and touchpoints to be reviewed by AMA.
- **Required agreements & registers** — The SI establishes and maintains, at minimum, an interface control register and interface agreements, a change-control process, a RAID log, and an incident and escalation process. The SI proposes how these operate; AMA approves the approach and receives the artefacts (see 5.4.6 Outcomes & Deliverables).

5.4.7 Assumptions, dependencies & AMA responsibilities

- **AMA responsibilities:** provide the steering committee and a focal point / owner per workstream; make timely decisions; provide access to systems, data and subject-matter experts; provide environments and funding; impose cooperation obligations on module vendors; and supply the requirements (Chapter 5).
- **Dependencies:** module vendors are selected and contracted with cooperation obligations; counterpart/source systems are ready to integrate (AMRH, ECRESS, AfriVigilance, AMA-SPOR, payment); and hosting meets data-residency requirements.
- **Assumptions:** the SI is to state any assumptions on which its plan and price depend; AMA and the SI will confirm or adjust these at the discovery gate.

5.4.8 Questions for vendors

These questions are the primary means by which AMA will understand the SI's capabilities. Vendors should answer each in Appendix B.

5.5 Capability / Component 5 - Portal & RIMS

Phasing for this component.

Phase 1 (MVP): the Sponsor Gateway, the reviewer view, and access/usability views.

Phase 2: the AMA internal Portal build-out, the configurable workflow engine, the full Market Authorization workflow, the billing view, the master-data intake/front-end view, and the vigilance view (AfriVigilance integration).

Context (Phase 3+): Scientific Advice, Clinical Trials, Lifecycle Management, the Inspections module, Lab Management, Licensing, and Expert Management; QMS is cross-cutting.

5.5.1 Overview and scope

5.5.1.1 Scope of activities

Module 5.5 covers AMA's Regulatory Information Management System (RIMS): the Portal, the Workflow engine, and the regulatory and enabling modules that manage the end-to-end regulatory lifecycle - submission through assessment, decision, and post-market oversight.

AMA is initially focusing on its Phase 1 (MVP) and Phase 2 regulatory capabilities. Prioritizing its own capabilities first and scaling to a continental system over time:

- **Phase 1 (MVP).** Stand up AMA's own core, the eCTD and the data/enterprise foundations - to enable Market Authorization intake and reviewer access/review.
- **Phase 2.** Stand up AMA's regulatory foundations (workflow engine, data foundations, and portal build out) and develop the full Market Authorization capability.
- **Phase 3+ (context).** Extend AMA's own modules across more regulatory functions (Scientific Advice, Clinical Trials, Lifecycle Management, Inspections, Lab Management, Licensing; QMS is cross-cutting), maturing the RIMS for AMA's full mandate.
- **Phase 3+ / Future (context).** Scale to a continental system - open the platform as optional NRA tenants, tiered by maturity, enabling reliance and continental coordination.

5.5.1.2 Building-block model

AMA RIMS is conceived as a modular, composable platform assembled from building blocks: a common AMA Portal, an eCTD layer, a Workflow Engine, and a set of regulatory function modules (Market Authorization, Clinical Trials, Inspections, Pharmacovigilance, etc.), all resting on the shared data and enterprise foundations established in Modules 2 and 3. Vendors responding to Module 5 must describe how their proposed RIMS architecture conforms to this building-block model and how it interoperates with the solutions delivered under Modules 1–4.

Each regulatory module (e.g., Market Authorization) is assembled from five shared foundations:

- **Portal** - configurable application / case-management platform and unified role-based surface. (5.5.2)
- **Workflow engine** - process orchestration, case management, and the DMN rules engine. (5.5.3)
- **eCTD** - dossier and document engine (5.1).
- **Data Standards & Integrations** - master data, integration, event mesh, and analytics. (5.2)
- **Enterprise Setup** - identity/access, hosting, and security. (5.3)

Modules use these foundations to differing degrees - some draw on the full stack, some on a subset (e.g., not all modules use the eCTD), and some are primarily integrations of systems that already exist. Each module's own section states which foundations it relies on; configuration sits on top.

The authoritative inventory of pre-built/existing systems to integrate (e.g., AfriVigilance, ERP) lives in Systems Integration (5.4.5); integration patterns and standards live in Data Standards & Integrations. Module sections cross-reference these rather than duplicating them.

5.5.1.3 Coverage and overlap with other systems

AMA's RIMS vendor must conform to the integration model established by the Systems Integrator to ensure connectivity across AMA systems

- **eCTD** - dossier validation, lifecycle management, and storage; 5.5 integrates with it, not duplicates it.

- **Data Standards & Integrations** - master data, analytics, event mesh, API gateway, and ERP/billing integrations consumed by the RIMS. (Transactional data is scoped and developed in the RIMS system by module ensuring adherence to master data and analytical requirements)
- **Enterprise Setup** - IAM, Case-Membership, hosting, and security; read and write where specified, not rebuilt.
- **Systems Integration** - SI coordination, cross-vendor integration, and migration delivery.

5.5.1.4 RIMS Procurement Approach

AMA allows vendors to submit proposals on the following options:

1. **Combined portal and workflow engine**
2. **Only portal**
3. **Only workflow engine**

Vendors submitting a proposal for only Option 2 or Option 3 must explain how they will ensure their solution is broadly compatible with other RIMS solutions and must provide a reference example demonstrating how they have previously integrated their solution into a wider system architecture.

5.5.1.5 Components at a glance

Shared building blocks

- **Portal** - configurable app/case-management platform and unified role-based surface; the shell modules extend. [Portal umbrella; MVP = Sponsor Gateway only]
 - **AMA Portal** – Configurable app/case-management platform for AMA usage; the shell modules extend to add AMA functionality [Phase 2]
 - **Sponsor Gateway** – MVP extension of the AMA portal; configurable externally facing for receiving regulatory submissions [Phase 1 (MVP)]
- **Workflow engine** - orchestration, case management, clocks/milestones, routing, centralized rules management. [Phase 2]

Regulatory modules (comprised of building blocks unless otherwise noted)

- **Market Authorization** - registration/listing of medicines: screening, assessment, LoQ cycles, decision, reliance. [Phase 2 · Assemble]
- **Scientific Advice** – formal engagement between sponsors and AMA for pre-authorization scientific advice; includes intake, screening, routing and engagement [Phase 3+ (context) · Assemble]
- **Clinical Trials** - clinical trial application submission, review, and decision/oversight. [Phase 3+ (context) · Assemble]
- **Lifecycle Management** - variations, renewals, and post-approval changes. [Phase 3+ (context) · Assemble]
- **Inspections** - GMP/site inspection planning, conduct, findings, CAPA, certification. [Phase 3+ (context) · Assemble]
- **Lab Management** - sample intake, testing, results, lot release (no LIMS; optional external-lab feeds). [Phase 3+ (context) · Assemble]
- **Licensing** - establishment and personnel licensing and registers. [Phase 3+ (context) · Assemble]
- **QMS** - controlled documents, SOPs, templates, training, internal CAPA, audits (cross-cutting). [Cross-cutting · Assemble]
- **Post-Market Surveillance (Vigilance)** - vigilance and signal detection, complaints, surveillance and enforcement. [Phase 2 · Integrate: AfriVigilance/HaloPV]

Enabling modules / views (comprised of building blocks unless otherwise noted)

- **Billing** - fee schedules, invoicing, payment, reconciliation; integrated with the Portal and ERP. [Phase 2 · Assemble and Integrate: ERP]
- **Master Data** – Data intake workflows and front-end view to visualize AMA SPOR data [Phase 2 · Assemble]
- **Expert management** – Centralized, validated database of continental expertise integrated into AMA's RIMS to support with reviewer assignment and scheduling [Phase 2 · Integrate and extend eCRES]
- **Access and useability** – essential views to system access and usage including account setup, configurations and front-page log-in (full list to be proposed by vendor) [Phase 1 (MVP)]
- Additional modules to be identified in design and future phases.

5.5.2 Sponsor and AMA portal (shared building block)

Primary case management and user interface of AMA's RIMS system. The portal manages all user interaction with AMA's systems, stores regulatory module transactional data and connects seamlessly with other foundational systems.

5.5.2.1 Scope of activities

Discovery:

- Vendor will map-out user journeys and validate requirements for AMA's Phase 1 (MVP) and Phase 2 portal extensions: Sponsor Gateway (Phase 1 (MVP)), Market Authorization, enabling views (Billing, Master Data) and user views (e.g., Admin, secretariate, AMA leadership, reviewer, user creation)
- Vendor will refine their proposed portal architecture based on the above journeys and requirements
- Vendor will validate and detail all potential user groups and corresponding portal requirements
- Vendor will refine its approach to develop AMA's portal foundations, Phase 1 (MVP) and Phase 2 scope
- Vendor will develop mock-ups of initial portal views and extensions

High-level development scope:

- AMAs portal is a configurable, extendable application platform and the single, role-based entry point for all regulatory work - one account, one surface, content varying by user.
- AMAs portal provides a user interface over the headless back-ends of other shared systems via their APIs/events (e.g., eCTD (documents), the Workflow engine (process and state), Data Standards & Integrations (data))
- AMA's portal hosts each module's domain/transactional records and forms, referencing canonical master data from Data Standards & Integrations and publishing transactional data and lifecycle events back to it (tagged with canonical identifiers; never siloed).
- AMA's portal does not own the access model or cybersecurity (Enterprise Setup, 5.3), process state/clocks/routing (Workflow engine, 5.5.3), master/reference data (Data Standards & Integrations, 5.2), dossier documents (the eCTD, 5.1), or module-specific surfaces (each module) - it consumes, composes, and presents them.

5.5.2.2 Functional requirements

Theme A - Role-based views

A single-entry point that composes role-based views from the shared access model, supporting multiple roles/contexts and session controls. Complete set of roles and views to be defined by vendor and AMA in discovery phase.

AMA intends these views to be generally extendable by regulatory module (e.g., the admin view may have a central overview landing page with new views added per regulatory module)

Theme B - Module extension & composition

Ensures modules plug in via a defined extension contract — independently deployable, fault-isolated, composed over back-ends with consistent UX and platform APIs.

Theme C - Application data & forms

Configurable data model, forms/views, system-of-record domain records, validation, rules-engine logic, master-data referencing, canonical-ID publishing, and record–document linkage/export

Theme D - No-code configuration & administration

A no-code admin surface for catalogues, forms/templates, workflow edits, users/entitlements, notifications, and dashboards, with safe change control and audit.

Theme E - Notifications, search & dashboards

Surfaces notifications/tasks, global search, operational dashboards and KPIs, help/support, and multilingual/accessible UX

Theme F - Multi-tenancy & NRA enablement

Multi-tenant architecture with per-tenant data isolation, configuration, identity, and maturity-tiered NRA profiles

Theme G – Sponsor Gateway

The sponsor gateway is an extension of the portal framework outlined above. The gateway is intended to be the initial extension of the AMA portal and required for AMA's MVP. The requirements are a non-exhaustive set of features to be refined in solution design.

5.5.2.3 Vendor service obligations

All vendor service obligations outlined in appendix C.

5.5.2.5 Vendor response questions

Vendors responding to this module are asked to answer response questions detailed in Appendix B.

5.5.3 Workflow engine (shared building block)

The configurable, auditable orchestration layer that executes AMA's regulatory and enterprise processes across modules and foundations (e.g., Market Authorization, and MDM), running multi-step, multi-actor processes against regulatory timelines under central oversight.

Key Design Principles.

1. **Low-/no-code policy and process configuration.** Allow AMA administrators to configure workflows, rules, roles, timelines, clock events, and milestones without code changes (preferably through the admin portal view)
2. **Configurable beyond AMA.** Avoid hard-coding AMA-specific processes so the platform can support future authorities, tenants, or instances.
3. **Case-centric execution.** Treat the case as the core process record, linking tasks, documents, decisions, timelines, external attributes, and audit history.
4. **API- and event-first interoperability.** Expose workflow state, actions, decisions, deadlines, and notifications through documented APIs and event contracts.
5. **Auditability by design.** Capture workflow events, assignments, decisions, approvals, and clock changes in a traceable, exportable audit record.

5.5.3.1 Functional requirements

Theme 1. Process & Case Orchestration

Definition and execution of regulatory processes as cases moving through multi-step, sequential, parallel and conditional paths involving multiple roles; creation and management of cases as the central process record; allocation, tracking and reassignment of tasks; participant notifications; and tracking and reporting of external data (e.g., NRA reliance status) against a case.

Theme 2. Regulatory Timeline & Clock Control

Configuration and enforcement of regulatory timelines against cases: clock start and stop, statutory and procedural deadlines, milestone scheduling, planned-vs-actual tracking, and deadline-driven alerts and escalation.

Theme 3. Workflow Configuration, Rules & Lifecycle

The design-time capability to define and change workflows and the business rules that drive routing, without code: authoring of steps, states, transitions, approval points and roles; the business-rules/routing engine; versioning of workflow and rule definitions; per-module process templates on a shared core; and the architectural separation that allows additional tenants/instances to be provisioned in future.

Theme 4. Workflow Audit, Traceability & Reporting

The evidentiary and oversight layer: an immutable record of workflow steps, decisions, approvals, assignments and clock events; exportable audit logs for regulatory purposes; and operational dashboards/reporting on clock status, throughput and workload.

5.5.3.2 Non-functional requirements

Workflow specific NFRs are listed in the Appendix C

5.5.3.3 Vendor service obligations

Vendor service obligations outlined above.

5.5.3.4 Vendor response questions

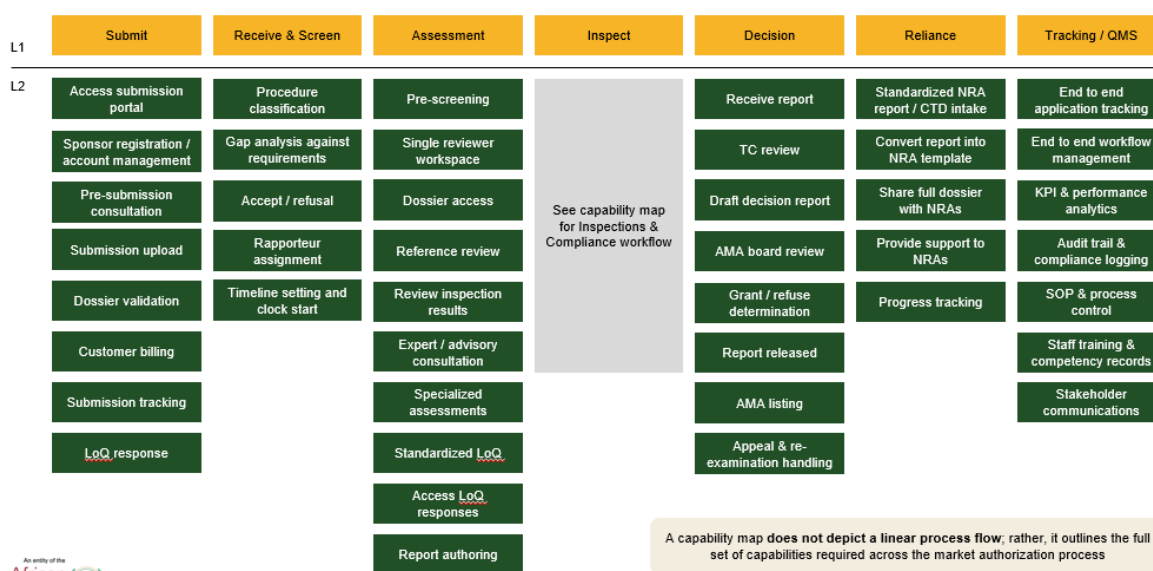
Vendors responding to this module are asked to answer response questions outlined in Appendix D.

5.5.4 Regulatory component - Market Authorization

5.5.4.1. Scope and process coverage

AMA will build an integrated Market Authorization (MA) module on the shared foundations (Sponsor Gateway, eCTD, workflow engine, and the shared data and enterprise foundations), configured for the centralized MA procedure for new product authorization. Lifecycle management (variations and renewals) is handled separately in 5.5.7; the detailed inspection process is handled in the Inspections module (5.5.9).

Market Authorization capability map



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Figure 1. Market Authorization L1 process stages; Tracking / QMS spans all stages.

The module will need to:

- 1. Configure submissions and sponsor data collection** through the Sponsor Gateway, including submission classification, handling, eAF and fee handling.
- 2. Screen and accept submissions** - procedure classification, completeness/gap analysis, accept/refuse, and timeline setting / clock start.
- 3. Facilitate the end-to-end MA process** from screening, assessment, LoQ cycles (with clock stops), re-review and decision.
- 4. Support secretariat and reviewer dossier access and review** through the eCTD reviewer view, including assessment report authoring.
- 5. Manage the LoQ cycle** - issue standardized lists of questions, receive consolidated responses, and handle the associated clock stops and restarts; the LoQ is the MA-specific form of the structured regulatory correspondence handled generically by the eCTD and Workflow engine.
- 6. Coordinate inspections where required** and incorporate results into the assessment (Inspections module, 5.5.9). At MVP, scope is limited to capturing structured inspection reports into AMA's data systems (per Section 2.3); coordinating inspections within MA assessment is Phase 2, and the full Inspections module is Phase 3+ context.
- 7. Support secretariat submission and process tracking** through the MA AMA portal view, including clock/milestone status and KPI reporting.
- 8. Support secretariat assignment of reviewers/rapporteurs** through the AMA portal (conflict-of-interest via expert management).
- 9. Coordinate AMA Technical Committees** - scheduling, document access, and capture of TC outputs - through the AMA portal.
- 10. Support the decision-making and issuance process** - draft decision from review/TC outputs, board review, grant/refuse, conditions/PMA commitments, authorized digital signature, immutable report, and AMA registry listing.
- 11. Automate decision sharing** with the public (sponsor portal and public registry) and with NRAs (report/template conversion, controlled disclosure, reliance tracking, notifications).

12. **Support appeals and re-examination** - structured intake, eligibility validation, and an appeal workflow/clock.

13. **Maintain end-to-end clock control, audit trail, and KPI/performance analytics** across the process.

Throughout, the module supports a lead NRA plus contributing NRAs, optional (reliance) participation, multi-cycle review with clock stops, and scalability to a growing number of participating countries.

5.5.4.2. Requirements

Requirements are grouped by the capability-map L1 stages and tagged to the shared component that delivers them, so a vendor bidding on part of the platform can identify the rows relevant to its scope.

Audit trail, clock mechanics, notifications, and access control are inherited from the shared foundations (Workflow Engine 5.5.3; Module 3) and are not restated here. Rows marked “interface” span components; ownership and coordination sit with the systems integrator (Module 4).

5.5.5 Regulatory component - Scientific Advice

AMA is not currently soliciting bids for its scientific advice module. The information below is to ensure outlined solutions account for future module requirements and provide AMA with an understanding on how proposed solutions may scale to support all of AMA's regulatory requirements.

5.5.5.1 Scope and process coverage

The Scientific Advice module supports structured pre-submission and developmental engagement between AMA (with participating NRAs and experts) and applicants: intake of advice requests and briefing documents, coordinated scientific and regulatory advice on development programs, study designs and evidence requirements, and issuance of documented advice ahead of a Market Authorization, Clinical Trial or lifecycle application. It enables coordinated, traceable advice across NRAs and experts while preserving national responsibilities.

5.5.5.2 Shared foundation extensions

- **Sponsor Gateway - submission** of advice requests and briefing packages, applicant communication, and meeting scheduling and tracking. Deviates: the interaction is a structured advice request and briefing package rather than a dossier, and the portal supports pre-submission meeting booking and agenda exchange.
- **AMA portal** – Screen incoming requests, assign to reviewers, draft advice and record audit trail
- **Workflow engine - configurable** advice workflows: request intake and triage, expert/NRA assignment, meeting scheduling, advice drafting and issuance, with time-boxed milestones.
- **Shared data / SPOR - advice** records linked to substance, product and organization master data and, where applicable, to subsequent MA, CT or lifecycle cases.
- **Enterprise / IAM - roles** and access for applicants, AMA scientific staff, external expert advisors, and participating NRA reviewers over central IAM. Deviates: external expert advisors and conflict-of-interest management are prominent, and advice-content confidentiality applies.

5.5.6 Regulatory component - Clinical Trials

AMA is not currently soliciting bids for its clinical trial module. The information below is to ensure outlined solutions account for future module requirements and provide AMA with an understanding on how proposed solutions may scale to support all of AMA's regulatory requirements.

5.5.6.1 Scope and process coverage

The Clinical Trials (CT) module supports authorization and oversight of clinical trials across the trial lifecycle: submission and approval of clinical trial applications, multi-country assessment coordination, and ongoing monitoring and status tracking. It enables coordination across NRAs while preserving national responsibilities.

5.5.6.2 Shared foundation extensions

- **eCTD** — Extends dossier handling to manage protocol- and IMP-centric submissions and their amendments using clinical-data standards (e.g., CDISC), aligning with eCTD where applicable rather than requiring a full eCTD dossier.
- **Sponsor Gateway** — Extends the applicant intake surface to receive clinical-trial applications and amendments from sponsors, CROs and principal investigators, and adds public trial-registration and transparency surfaces.
- **AMA portal** — Extends the internal staff surface with multi-country assessment coordination, parallel scientific- and ethics-review tracking, and ongoing trial-status monitoring after authorization.
- **Workflow** — Extends the engine with parallel ethics and regulatory review paths and an ongoing-conduct phase (amendments and safety reporting) layered onto the initial-authorization flow.
- **Data Foundations / SPOR** — Extends master data with trial, IMP and site records linked to trial-registry identifiers (WHO ICTRP / PACTR) and to E2B safety reporting, with heightened protection for participant data.
- **Enterprise / IAM** — Extends the access model with ethics committees / IRBs as a distinct external participant type and stronger confidentiality controls for participant data.

5.5.7 Regulatory component - Lifecycle Management (variations and renewals)

AMA is not currently soliciting bids for its lifecycle management module. The information below is to ensure outlined solutions account for future module requirements and provide AMA with an understanding on how proposed solutions may scale to support all of AMA's regulatory requirements.

5.5.7.1 Scope and process coverage

The Lifecycle Management module supports post-authorization activities for products that already hold a market authorization: variations (Type IA/IB/II equivalents as applicable), renewals and periodic reassessments, and other regulatory updates. It integrates tightly with existing MA records and product data so that every change is tracked against the parent authorization.

It reuses the shared foundations and differs from Market Authorization mainly in volume and shape: large numbers of smaller, often low-complexity submissions linked to a parent MA, with variation categories that drive differentiated and often accelerated timelines, and lifecycle-aware document versioning rather than first-time dossier intake.

5.5.7.2 Shared foundation extensions

- **eCTD** — Extends dossier handling with lifecycle-aware versioning, receiving new sequences against an existing parent dossier rather than first-time intake.
- **Sponsor Gateway** — Extends the applicant intake surface, so each submission is linked to an existing parent MA, with the applicant selecting a variation category that drives the path. Sponsors can track the product lifecycle through the AMA portal (e.g., see when inspections are scheduled)
- **AMA portal** — Extends the internal staff surface to manage varying types of post-authorization cases, each tracked against its parent authorization.
- **Workflow** — Extends the engine with variation-category-driven workflows and reduced or accelerated timelines for high-volume, low-complexity cases.
- **Data Foundations / SPOR** — Extends product master data so every variation or renewal updates the parent product record with full change history and lineage.
- **Enterprise / IAM** — Extends the access model using largely the same applicant and assessor roles as Market Authorization, with a lighter footprint.

VQ-5.5.7-B - Record consistency. Describe how lifecycle changes keep MA records and product data (SPOR) consistent, indicating what is available today versus roadmap.

5.5.8 Regulatory component - Post-Market Surveillance

AMA is not currently soliciting bids for its post-market surveillance module. The information below is to ensure outlined solutions account for future module requirements and provide AMA with an understanding on how proposed solutions may scale to support all of AMA's regulatory requirements.

5.5.8.1 Scope and process coverage

The Post-Market Surveillance module supports safety monitoring of authorized products: collection and management of safety signals, cross-border signal detection and analysis, and the assessment and escalation of safety issues. It integrates with pharmacovigilance systems (e.g., AfriVigilance) and with NRA systems.

It reuses the shared foundations but is more event-driven than the application-based modules: rather than a single submission-to-decision flow, it continuously ingests and processes safety data from external systems, manages signals through detection, validation, assessment and escalation, and exchanges data bidirectionally with PV and NRA systems in near real time.

5.5.8.2 Shared foundation extensions

- **eCTD** — Extends document handling to manage safety reports and signal records, with dossier-style eCTD submission largely not used in this module.
- **Sponsor Gateway** — Extends the applicant intake surface as a lighter touchpoint for safety-report submission and access to alerts, since most input arrives through system integration (E2B).
- **AMA portal** — Extends the internal staff surface with signal review, assessment and escalation views over continuously ingested safety data.
- **Workflow** — Extends the engine with event-driven signal workflows (detection, validation, assessment and escalation) triggered by inbound events rather than applicant submissions.
- **Data Foundations / SPOR** — Extends master data with safety and signal records linked to product and organisation data, supporting near-real-time bidirectional exchange with AfriVigilance and NRA systems.
- **Enterprise / IAM** — Extends the access model with external pharmacovigilance reporters and NRA vigilance units as additional actors under high-availability and data-sensitivity controls.

5.5.9 Regulatory component - Inspections

5.5.9.1 Scope and process coverage

The Inspections module supports planning and scheduling of inspections, execution and recording of inspection outcomes, and tracking of findings and corrective and preventive actions (CAPA). It covers inspection types such as GMP, GDP and GCP, and interactions with inspectors and regulated entities.

It reuses the shared foundations and differs from the application modules in its field orientation: inspections are executed on-site, often by mobile and where possible offline-capable inspectors; the regulated entity (manufacturer or site) is a key participant; and outcomes feed CAPA tracking and link back to MA records and SPOR organization/site data.

The module shall support the following core capabilities:

- Inspection planning, scheduling, notification, and inspector assignment
- On-site execution with checklist-driven evidence capture (notes, photos, documents)
- Findings capture and structured inspection reporting
- CAPA submission, review, timeline tracking, and verified closure
- End-to-end inspection tracking and audit, with links to MA records and SPOR organisation/site data

5.5.9.2 Shared foundation extensions

- **eCTD** — Extends document handling to manage inspection plans, reports and CAPA evidence, link inspection documents to the relevant MA case and SPOR site/organization.
- **Sponsor Gateway** — Extends the applicant intake surface, so the regulated entity (site or manufacturer) is the principal external user for document exchange, in place of a marketing-authorization sponsor.
- **AMA portal** — Extends the internal staff surface with inspector scheduling, document upload / exchange, resourcing and field-oriented access, (where possible offline-capable).
- **Workflow** — Extends the engine with the inspection lifecycle (planning, execution, reporting and follow-up), including CAPA tracking loops.
- **Data Foundations / SPOR** — Extends master data so organization and site records are central, with findings linked back to products and sites.
- **Enterprise / IAM** — Extends the access model with regulated-entity access as a distinct role and mobile or offline access for inspectors.

5.5.9.2 Functional requirements

Theme A – Inspection planning and scheduling

This theme covers the capabilities required to initiate, plan, and schedule inspections and to notify and coordinate with regulated entities. It ensures inspections are resourced and scoped using site profile and inspection history before execution.

Theme B – Inspection execution and evidence capture

This theme covers on-site execution of inspections against standard checklists and the capture of supporting evidence. It ensures inspection activity, findings, and evidence are recorded consistently against the inspection record.

Theme C – Findings and inspection reporting

This theme covers the drafting, review, finalization, and issuance of inspection outcomes, and the structured capture of reports and findings into AMA's data systems. The structured report-capture and findings-register capabilities form the MVP foundation.

Theme D – CAPA management

This theme covers the corrective and preventive action loop with the regulated entity, from CAPA submission through review, tracking, and verified closure of findings.

Theme E – Compliance tracking, audit, and regulatory data links

This theme covers end-to-end tracking of inspections, the audit trail, and the links between inspection records and other regulatory data (MA records, SPOR organization/site data). The inspection register, regulatory data links, and audit trail form the MVP foundation ("data intake and tracking foundations").

5.5.10 Regulatory component - Lab Management

AMA is not currently soliciting bids for its laboratory management module. The information below is to ensure outlined solutions account for future module requirements and provide AMA with an understanding on how proposed solutions may scale to support all of AMA's regulatory requirements.

5.5.10.1 Scope and process coverage

The Lab Management module supports coordination and tracking of laboratory testing of medical products: requesting and scheduling tests, sample management, and recording and reporting of results. It integrates with regulatory workflows such as Market Authorization and Inspections so that testing can be initiated from, and results fed back into, regulatory decisions.

It reuses the shared foundations and differs in being request- and sample-driven rather than submission-driven: testing is typically initiated by other modules or AMA staff rather than by an external sponsor, and the module manages samples and laboratory results (LIMS-style), returning structured outcomes to the requesting process.

5.5.10.2 Shared foundation extensions

- **eCTD** — Extends document handling to manage test requests, methods and result documents, with dossier-style eCTD submission not used in this module.
- **Sponsor Gateway** — Extends the applicant intake surface only lightly, since testing is generally initiated internally rather than by an external applicant.
- **AMA portal** — Extends the internal staff surface with laboratory- and requester-facing views for test requests and result access, with AMA and NRA staff and laboratories as the primary users.
- **Workflow** — Extends the engine with sample- and request-driven testing workflows (request, sample handling, testing, result recording and return) triggered by other modules such as MA, Inspections and lot release.
- **Data Foundations / SPOR** — Extends master data with LIMS-style sample, test and result records linked to product and laboratory data and back to the originating regulatory case.
- **Enterprise / IAM** — Extends the access model with laboratory staff as primary users and potential integration with external or contract laboratories.

5.5.11 Enabling module - Billing

5.5.11.1 Scope and process coverage

The Billing module shall support the definition, calculation, tracking, and reconciliation of financial charges associated with AMA regulatory services.

The module shall function as an enabling capability across the AMA platform, ensuring that all billable regulatory activities are systematically translated into traceable financial transactions and that payment status is visible within the end-to-end regulatory process.

The module shall support the following core capabilities:

- Maintenance of fee schedules and pricing rules for regulatory services
- Calculation of fees based on service type, case complexity, or other defined criteria (integration with Sponsor Gateway)
- Generation and tracking of invoices
- Integration with a 3rd party payment service
- Reconciliation between billing data and enterprise finance systems
- Read and write payment status / requests from AMA event mesh

5.5.11.2 Shared foundation extensions

Sponsor Gateway: The solution shall be integrated with the sponsor-facing portal to calculate and share AMA fees with the sponsor. The sponsor shall receive notifications on the status of their invoices and payments.

AMA portal: The solution shall integrate with the AMA portal to showcase payment status across applications. The solution shall have specific stakeholder views:

- **AMA Admin:** Update AMA fee table, add / remove fees and develop new service types with corresponding fees
 - AMA admin shall be able to update the complete the above requirements with no-code configuration
 - The solution shall develop an update control protocol to ensure at least two admin sign off on fee changes

- The solution shall capture a traceable audit record of historic fees in alignment with AMA's data retention policy

Public webpage: The solution shall maintain an up-to-date listing of AMA's fees on their publicly facing webpage

Workflow engine: The Billing module shall use the shared Workflow Engine to support:

- triggering of billing events from regulatory processes
- automated or semi-automated invoice generation following billable events
- updates to billing and payment status throughout the lifecycle
- propagation of payment status into dependent workflows

5.5.11.3 Functional and non-functional requirements

Functional requirements

Theme A – Fee schedules and charging logic

Fee schedules support creation and maintenance of pricing for regulatory services, calculating fees based on service types and defined pricing rules. Charges are linked to billable events from regulatory workflows, with configurable logic allowing fee rules to be updated over time.

Theme B – Invoicing and payment tracking

Invoicing and payment tracking generates invoices for billable regulatory services and manages their full lifecycle from creation to closure, while monitoring payment status across all invoices. Invoice and payment information is exposed to authorized users through the Portal for transparent, self-service visibility

Theme C – ERP integration and reconciliation

ERP integration and reconciliation connect billing with Finance/ERP systems, supporting reconciliation between billing data and financial records and maintaining traceability across services, invoices, and payments. Billing data is handed over to ERP reporting processes for consolidated financial oversight.

Theme D – Workflow and case integration

Workflow and case integration embeds billing within regulatory operations by linking billing records to cases and services, receiving billable events from workflows, and propagating payment status back to them. Operational dashboards provide visibility into billing status and outstanding payments across active work.

Theme E – Auditability and controls

Auditability and controls ensure billing integrity by maintaining a complete audit trail of all billing actions and end-to-end traceability from service to payment. Access to billing data is tightly controlled, supporting compliance, accountability, and secure financial oversight.

Non-functional requirements

See non-functional requirements in appendix C

5.5.12 Enabling module - MDM

5.5.12.1 Scope and process coverage

The Master Data Management (MDM) module shall provide the front-end, workflow, and operational layer required to create, manage, validate, and govern master data entities across the AMA Digital Platform.

While the underlying master data structures and services (AMA-SPOR) are defined and technically implemented within the Data Foundations and Integrations module (Module 2), this module provides the user-facing and process-driven capabilities required to operationalize master data management across regulatory workflows.

The MDM module shall function as an enabling capability across all AMA regulatory modules, ensuring that master data is consistently created, reviewed, governed, and reused throughout the regulatory lifecycle.

The module shall support the following core capabilities:

- Capture and maintenance of master data records across all core domains (Products, Substances, Organizations, Referentials)
- Workflow-driven creation, validation, and approval of master data entries
- Integration of master data creation and updates within regulatory processes (e.g., submission intake)
- Support for data stewardship roles and governance workflows
- Management of data versioning, lineage, and auditability
- Exposure of master data in user-friendly views for regulatory stakeholders

The MDM module shall operate as a workflow-enabled front-end layer on top of AMA-SPOR, ensuring that:

- master data is not siloed within individual modules
- all master data changes follow governed processes
- master data becomes a shared, authoritative asset across the AMA ecosystem

5.5.12.2 Portal, eCTD, and workflow configuration requirements

Portal

The MDM module shall integrate with the AMA Portal to provide:

- Dedicated user interfaces for: Data stewards, AMA operational users, Regulatory reviewers (read access where appropriate)
- Configurable forms for: Creating and updating master data entities, Reviewing and approving data changes
- Role-based access to master data records and workflows
- Visibility of master data usage across regulatory processes (e.g., linked cases, submissions)

eCTD

The MDM module shall integrate with the eCTD module as follows:

- Validation of submission data against existing master data
- Creation or enrichment of master data records based on submission inputs (following designated workflows)
- Maintenance of linkage between eCTD dossiers and corresponding master data entities

The MDM module shall ensure that:

- master data created through submissions becomes part of the governed SPOR dataset
- no duplication or divergence of data occurs between submission data and master data records

Workflow engine

The MDM module shall use the shared Workflow Engine to support:

- Data mgmt. and lifecycle workflows, including: creation, validation, approval / rejection, enrichment
- Assignment of tasks to data stewards and responsible roles
- Multi-step approval workflows for sensitive or critical data
- Audit trail of all changes and approvals
- Integration of master data workflows with regulatory processes (e.g., submission intake, review, inspections)

The module shall support:

- configurable workflows per data domain
- rule-based routing of data-change requests
- event-based updates to other modules when master data changes

5.5.12.3 Functional and non-functional requirements

Functional requirements

Theme A – Master data capture and maintenance

This theme covers the core capabilities required to create, update, and manage master data entities within the AMA-SPOR model. It ensures that all key data domains (e.g., products, substances, organizations) are maintained as structured, version-controlled, and interrelated records that can be consistently reused across regulatory workflows.

Theme B – Data governance and workflows

This theme defines the governance and workflow mechanisms required to ensure that all master data changes are controlled, validated, and auditable. It includes data stewardship roles, approval processes, and data quality controls needed to maintain a single, authoritative source of truth across the AMA Digital Platform.

Theme C – Integration with regulatory workflows

This theme focuses on the integration of master data management with regulatory processes across the AMA platform. It ensures that master data is captured, enriched, and reused seamlessly within submission, review, and regulatory decision workflows, enabling consistency and eliminating data duplication across modules.

Theme D – Data visibility and access

This theme covers the capabilities required to access, search, and visualize master data across the platform. It ensures that different user groups can efficiently retrieve and understand master data through role-based access, user-friendly views, and traceable links to regulatory processes and system usage.

5.5.13 Enabling module – Expert Management

5.5.13.1 Scope and process coverage

The Expert Management module shall provide a centralized capability to manage, validate, assign, and monitor the network of regulatory experts supporting AMA's federated operating model. This module is critical to enabling AMA's reliance-based approach, where scientific assessments are conducted by a distributed pool of experts across multiple NRAs and institutions. AMA is not currently procuring this module.

The module shall function as an enabling capability across all regulatory workflows, ensuring that appropriate experts are identified and assigned to regulatory processes, conflicts of interest are managed, expertise is validated and traceable and expert contributions are recorded and auditable

5.5.13.2 Portal, eCTD, and workflow configuration requirements

Portal

The Expert Management module integrates with the AMA Portal to provide expert-facing interfaces (profile management, availability, participation tracking) and AMA user interfaces (search, selection, assignment, and qualification/conflict-of-interest validation). It supports role-based access, advanced expert search and filtering, utilization dashboards, and transactional data storage.

eCTD

Rather than managing dossier content directly, the module integrates indirectly with the eCTD module by enabling assignment of experts to dossier reviews, linking their contributions to specific regulatory submissions, and ensuring traceability of each expert's assessments.

Workflowengine

The module uses the shared Workflow Engine to run expert onboarding, validation, and conflict-of-interest

workflows, and to manage assignment processes (selection, approval, notification, acceptance). It also tracks and records expert participation and inputs, with configurable assignment logic (expertise, workload, geography) and integration into regulatory workflow steps.

5.5.14 Enabling module - QMS

AMA is not currently soliciting bids for its quality management module. The information below is to ensure outlined solutions account for future module requirements and provide AMA with an understanding on how proposed solutions may scale to support all of AMA's regulatory requirements.

5.5.14.1 Scope and process coverage

The Quality Management System (QMS) module provides the controlled framework that governs how AMA performs its regulatory work: controlled documents and SOPs, staff training and competency, deviation and internal CAPA handling, and internal audit. In line with AMA's digital strategy, it covers policies and controls, deviation tracking and auditability, and operates as a cross-cutting capability across all regulatory modules.

It reuses the shared foundations and differs from the regulatory modules in being internally focused: it governs AMA's own procedures, staff and quality records rather than external sponsor submissions. Unlike the Inspections module, which manages external findings and manufacturer CAPA, it manages AMA's internal deviations and CAPA.

5.5.14.2 Shared foundation extensions

- **eCTD** — Extends document handling to a controlled internal library of policies, SOPs and templates with versioning, approval and effective-dating; dossier-style eCTD submission is not used in this module.
- **Sponsor Gateway** — Extends the applicant intake surface only minimally, since the QMS is internally focused rather than driven by external sponsors.
- **AMA portal** — Extends the internal staff surface with authoring, review and approval of controlled documents and with training, deviation/CAPA and internal-audit views for AMA and, where applicable, NRA staff.
- **Workflow** — Extends the engine with quality workflows for document lifecycle, training, deviation/CAPA and internal audit, with configurable routing, reminders and escalation.
- **Data Foundations / SPOR** — Extends master data with controlled-document, training, deviation/CAPA and audit records, linked to the procedures, staff and cases they concern.
- **Enterprise / IAM** — Extends the access model with quality, process-owner and auditor roles, and can link training/competency status to task permissions.

Chapter 6 - Response Format and Vendor Questions

This chapter defines the required structure, content, and expectations for vendor responses to ensure consistency, comparability, and alignment with AMA requirements. Vendor clarification questions are submitted under the process and deadlines in Section 3.4 (questions due 26 August 2026; consolidated responses published 31 August 2026, per Section 3.2).

6.1 Administrative Requirements

Vendors shall comply with the following administrative requirements when submitting their response:

- All responses shall be submitted in English
- Responses shall follow the structure defined in Section 6.2
- Vendors shall provide complete and unambiguous responses; partial or unclear responses may be evaluated as non-compliant
- All assumptions, dependencies, and constraints shall be explicitly stated
- Vendors shall clearly distinguish between:
 - standard (out-of-the-box) capabilities
 - configurable elements
 - custom development

6.2 Required Response Format and Foundation-Level Structure

Responses must reflect the staged award and phase boundaries set out in the Guide for Respondents (“Phasing and staged award”) and Section 2.5. Each module response shall break down the proposal by phase, and pricing shall be presented as separate Phase 1 and Phase 2 schedules per Section 6.6.

A. Global response structure

Each proposal shall contain:

1. Compliance checklist
2. Executive summary (Maximum 5 pages)
3. Corporate profile and qualifications

And per each component:

4. Solution overview
5. Experience, Case Studies and References
6. Technical and delivery approach
7. Integration approach
8. Component specific questions
9. Work plan, governance, and timeline
10. Staffing and key personnel
11. Exceptions and risks
12. Pricing and commercial response
13. Declaration of no Conflict of interests

B. List of appendix items

- A. Appendix A. (For reference) Vendor Submission Checklist
- B. Appendix B. Expression of Interest Form
- C. Appendix C. General Response Template (All responses must be complete)
- D. Appendix D. AMA Requirements Catalogue (See attached MS Excel sheet)
- E. Appendix E. Bid submission form (Technical Proposal)
- F. Appendix F. Commercial Pricing Register (See attached MS Excel sheet)
- G. Appendix G Declaration of no conflict of interests and no debarment.
- H. Appendix H. Reference project form
- I. Appendix I. Key Personnel CV summary template
- J. Appendix J. Statement of availability
- K. Appendix K. Consortium/joint venture declaration

AMA will accept additional additive submissions if they are complementary to the vendor's required responses.

Note on invoicing and payment: under any resulting contract, invoices are addressed to AMA with a copy to Garnet Partners Ltd. Garnet, as Fiscal Administrator funding this engagement, verifies each invoice for financial accuracy and compliance with the approved payment schedule and processes payment following AMA's written acceptance of the corresponding milestone or deliverable. Vendors' commercial responses should assume this milestone-based, acceptance-driven payment mechanism.

6.3 Orals, Demonstrations, and Interview Requirements

Select responding vendors will be invited to demonstrations and interviews. Vendors may be required to:

- Deliver solution demonstrations related to the module(s) they are bidding on
- Present on any of the topics outlined in the submission including solution architecture, implementation roadmap, change management and module specific questions
- Participate in Q&A sessions with AMA digital and regulatory stakeholders.

Submission Forms and Appendices

The following standard forms and templates shall be completed and submitted as part of the proposal. Bidders must use these formats without alteration to their structure. Fields shown in square brackets or blank cells are to be completed by the bidder

Appendix A - (For reference) Vendor submission checklist

See attached MS Word document

Appendix B - Digital Platform EOI-RFP

Form I-2 — Component Bid & Sub-contracting Declaration

Bidder identification

Bidder (prime / lead vendor) legal name:

Country of registration:

Primary contact (name):

Contact email / phone:

Date of declaration:

1. Purpose of this form

This form records each bidder's component-level intention to bid and its proposed delivery arrangement for the AMA Digital Platform procurement. The procurement is organised around five discrete components, and bidders may respond to one or more of them. For every component, the bidder must indicate whether it intends to submit a proposal, the capacity in which it will bid (as a single entity, as a prime with sub-contractors, or as a member of a consortium), and the identity and role of any sub-contractors or consortium partners on which it intends to rely. This form does not replace the Intent to Respond required under Section 3.5; it consolidates the component-level bid declaration and the partner disclosure that must accompany the bidder's proposal. A registered Intent to Respond is a precondition for submission — proposals submitted without a prior Intent to Respond will not be accepted.

2. AMA component and sub-contracting rules

AMA is running a modular, competitive procedure and will evaluate and award each component independently, on its own merits, to the strongest qualified bidder; cross-component partnerships are welcomed but not required. Bidders may partner or form consortia wherever this strengthens their ability to deliver a component. For each component bid, a single lead (prime) vendor must be clearly identified and will be AMA's primary contractual counterparty for that component. All sub-contractors and consortium partners must be disclosed, and the prime vendor remains fully responsible for the performance of every sub-contractor and partner it names. A vendor may bid as prime on one component and as a sub-contractor on another. AMA reserves the right to conduct due diligence on any named sub-contractor or partner, and any material change to a bidder's consortium or sub-contracting arrangement after the Intent to Respond deadline must be approved by AMA in writing. Bidders should note that Component 5 (Portal & RIMS) is evaluated as optional scope and assessed independently; where a bidder offers only part of Component 5, it should use the module breakdown in Section 4 to identify the specific modules bid.

3. How to complete

- Mark "Yes" against each component you intend to bid, and tick the capacity in which you are bidding it.
- Name every sub-contractor or consortium partner and describe the specific role or scope each will perform. Add rows if needed.
- If you are bidding any part of Component 5, also complete the Component 5 module breakdown in Section 4.

- Sign the declaration in Section 5. Each named sub-contractor / partner must countersign its acknowledgement block.

4. Component bid declaration

Component and core scope	Bidding on this component?	Bidding as	Named sub-contractor(s) / consortium partner(s)	Role / scope each will perform (NA if not sub-contracting)
Component 1 — eCTD (v4.0) Electronic submission and reviewer workspace for dossier assessment: eCTD intake portal, AS4 gateway, validator, reviewer workspace, LoQ workflow, secretariat tools.	☐ Yes ☐ No	☐ Single entity ☐ Prime + sub-contractor(s) ☐ Consortium member		
Component 2 — Data Standards & Integrations Master data, terminology and interoperability across regulatory systems: MDM / AMA-SPOR, IDMP alignment, ERP/billing integration, API gateway, HL7/FHIR standards.	☐ Yes ☐ No	☐ Single entity ☐ Prime + sub-contractor(s) ☐ Consortium member		
Component 3 — Enterprise Setup Identity, hosting, security and productivity foundations: IAM/SSO, cloud infrastructure, SIEM, backup & DR, Microsoft 365 configuration.	☐ Yes ☐ No	☐ Single entity ☐ Prime + sub-contractor(s) ☐ Consortium member		
Component 4 — Systems Integration Multi-vendor orchestration, integration architecture and delivery governance: SI scope, sub-contractor model, NRA connectors, API layer, integration governance/RACI. Prime SI capability strongly recommended.	☐ Yes ☐ No	☐ Single entity ☐ Prime + sub-contractor(s) ☐ Consortium member		
Component 5 — Portal & RIMS (optional scope) Regulatory Information Management assessed independently: submission portal, workflow engine, and regulatory/enabling modules. If bidding only part, complete the Component 5 breakdown in Section 4.	☐ Yes ☐ No	☐ Single entity ☐ Prime + sub-contractor(s) ☐ Consortium member		

5. Component 5 (Portal & RIMS) module breakdown

Complete this table only if you marked “Yes” against Component 5 above. Component 5 is optional scope and each module is assessed independently, so indicate exactly which modules you are bidding. The capacity (single / prime+sub / consortium) declared for Component 5 in Section 4 applies to all modules ticked here unless stated otherwise in the role column.

Component 5 module	Bidding?	Named sub-contractor(s) / partner(s)	Role / scope each will perform
Shared building blocks			
5.5.2 Sponsor & AMA Portal	☐ Yes ☐ No		
5.5.3 Workflow Engine	☐ Yes ☐ No		
Regulatory modules			
5.5.4 Market Authorization	☐ Yes ☐ No		
5.5.9 Inspections	☐ Yes ☐ No		
Enabling modules			
5.5.11 Billing	☐ Yes ☐ No		
5.5.12 Master Data Management (MDM)	☐ Yes ☐ No		

6. Declaration and signatures

I confirm that the information in this form is accurate and complete, that I am authorized to make this declaration on behalf of the bidder, and that, as prime / lead vendor, we accept full responsibility for the performance of all sub-contractors and consortium partners named above, in accordance with RFP Section 3.6.

Prime / lead vendor — authorized signatory

Organization (prime / lead vendor):

Authorized signatory (name):

Title / position:

Signature:

Date:

Sub-contractor / consortium partner acknowledgements

Complete one block for each named sub-contractor or consortium partner. Copy the block for any additional partners.

Sub-contractor / consortium partner 1

Partner organisation (legal name):

Component(s) / module(s) supported:

Role / scope to be performed:

Authorized signatory (name):

Title / position:

Signature:

Date:

Sub-contractor / consortium partner 2

Partner organisation (legal name):

Component(s) / module(s) supported:

Role / scope to be performed:

Authorized signatory (name):

Title / position:

Signature:

Date:

Sub-contractor / consortium partner 3

Partner organisation (legal name):

Component(s) / module(s)
supported:

Role / scope to be
performed:

Authorized signatory (name):

Title / position:

Signature:

Date:

Appendix C - General Response Template

PRIORITY APPENDIX — This is the most critical vendor deliverable. Non-compliance with this template will result in disqualification from detailed evaluation.

All vendors must complete part A with an additional part B filled out for each foundation described in Chapter 5. Sections must not be omitted; where a section is not applicable, vendors shall state the reason. Vendors are welcome to submit supplemental documentation where applicable to aid their response to each section. All supplemental documentation should clearly indicate which section(s) they apply to.

Part A — Completed Once Per Bidder

Part A is completed once per bidder, irrespective of the number of capabilities bid.

A1 Executive Summary

Vendors shall provide a concise executive summary including:

- Overview of proposed solution
- Key differentiators
- Alignment with AMA objectives
- Summary of implementation approach
- Summary of risks and mitigation

The executive summary shall not exceed a defined 5 pages.

A2 Corporate Profile and Qualifications

Vendors shall provide the corporate profile fields below (RFP Section 6.4) and shall evidence each mandatory minimum qualification (RFP Section 4.2). Assertions without supporting documentation will not be accepted.

- Company overview and ownership structure
- Presence in Africa (regional capability is particularly relevant)
- Experience with regulatory systems, large-scale public sector platforms, and multi-country deployments
- Certifications (if applicable), including security and compliance (e.g. ISO)

Mandatory Minimum Qualifications (RFP Section 4.2)

Qualification Area	Minimum Requirement (per RFP Section 4.2)	Vendor Evidence Provided	Document Reference
Legal standing	Legally registered entity in good standing; no active debarment (AU, UN, World Bank or equivalent)		
Relevant sector experience	At least three completed implementations in regulatory, health or public-sector digital platforms, at least one serving a multi-country or regional user base		
eCTD / regulatory systems expertise	Module 1 bidders: eCTD v4.0 deployment incl. submission validation,		

Qualification Area	Minimum Requirement (per RFP Section 4.2)	Vendor Evidence Provided	Document Reference
	reviewer workspace, lifecycle management		
Data and integration capability	Module 2 bidders: MDM, IDMP-aligned data standards or comparable regulatory master data programs		
Cloud and security baseline	Module 3 bidders: ISO 27001 and ISO 27701 or equivalent; deployment on compliant cloud infrastructure		
Financial capacity	Audited accounts or equivalent financial disclosure for the most recent two fiscal years		

A2 General Service Obligations

Vendors shall respond to each general service obligation (SO-GEN-*) set out in Appendix C using the excel sheet in Appendix C

Part B — Repeated For Each Capability / Module Bid

Part B is completed once for each capability / module bid. Sections retained in their existing document position are labelled with their target number.

B1 Solution Overview

- Description of the proposed foundation and its core capabilities
- Alignment with AMA scope and stated objectives
- Key differentiators relative to competing approaches

B2 Experience, Case Studies, References, Exceptions and Conflicts

Vendors shall provide at least two relevant case studies and two references for the foundation they are bidding on. Preference is given to examples in Africa and/or with large medicines regulatory agencies. Both case studies and references must be from public sector organizations only. Vendors shall tag each case study and each reference to the module(s) it evidences.

Case Studies (minimum 2)

Organization	Country / Region	Description of Engagement	Scale and Complexity	Outcome / Result	Module(s) Evidenced
Case Study 1					
Case Study 2					

B3 Requirements Compliance

Complete this capability's tab in the Functional & NFR requirements workbook in Appendix C. Do not restate requirements here. For specified requirements (see excel for instructions) vendors are required to provide a brief explanation of how they intend to meet that requirement.

B3 Module-Specific Service Obligations

Vendors shall respond to each module-specific service obligation listed in the Functional & NFR requirements workbook (if applicable)

B4 Technical and Delivery Approach

How does vendor's solution and approach align with and enforce AMA's digital guiding principles? (List in appendix)

How does vendor's solution align with AMA's outlined digital strategy (chapter 2)? Are there any areas where you would suggest AMA reconsider its approach?

How will vendor's solution scale to meeting AMA's digital target state? How will you ensure compatibility with future (phase 3) requirements? (e.g., multi-tenant access, low-code configuration)

B5 Integration Approach — Capability-Specific:

Vendors shall describe how their proposed solution integrates with AMA's target digital architecture and guiding principles outlined in Chapter 2. Some questions may not be applicable for specific components.

Questions:

- **Integration with the AMA Portal:** Describe how your solution exposes capabilities to be consumed via a unified, role-based portal, without duplicating UI or access logic?
- **Integration with the Workflow Engine:** Explain how your solution participates in case-based workflows, including how it consumes and emits workflow states, tasks, and events.
- **Integration with Data Foundations (AMA-SPOR and integration layer):** Describe how your solution uses and contributes to the shared master data model, including API-based access and event-driven data exchange aligned with AMA-SPOR and interoperability standards.
- **Integration with external and NRA systems:** Describe how your solution supports integration with heterogeneous NRA environments (API, file-based, or hybrid), in line with AMA's federated operating model.
- **Alignment with System Integrator (SI) model:** Explain how your solution will be delivered and integrated under SI coordination, including dependencies, interfaces, and responsibilities.
- **Extension of foundational systems.** How can your solution be extended to address the capabilities outlined in each of the regulatory components? (Focus primarily on Market Authorization, Inspections, MDM and Billing)
- **Integration and solution architecture.** Provide a solution architecture diagram (PNG or PDF) as a named attachment (make sure to highlight integration interfaces)

B6 Capability-Specific Questions

Vendors shall answer the question block below for the capability to be bid.

B5.2 eCTD (RFP Section 5.1.5)

Vendors responding to this module are asked to answer the following:

1. Openness / headless. How does your eCTD expose document management, lifecycle views, rendering, and annotation/review-metadata via documented APIs (OpenAPI 3.1) such that AMA could build its own

reviewer workspace on top without loss of capability or re-platforming? Provide a reference where a third party built a front end on your platform.

2. Workspace at MVP. Describe the reviewer/Secretariat workspace provided out of the box, and how review work created in it (annotations, leaf statuses) stays portable if AMA later replaces the UI.

3. Validation & Module 1. How is your validation engine configured to AMA's Module 1 and validation criteria, maintained by the authority without code changes (how can it be configured for NRA tenants in the future?)? Do you provide a industry pre-submission validation tool?

4. Access & integration. How does the solution consume external authentication (OIDC) and an external authorization/case-membership source for leaf-level enforcement, and emit lifecycle events to an external workflow engine - without requiring its own identity store or embedded workflow?

5. Multi-tenant eCTD. AMA intends to offer the eCTD as a shared service to NRAs of differing maturity. How does your solution support multi-tenant / multi-NRA operation — tenant-isolated data and configuration, per-tenant Module 1 profiles and validation rules, and per-tenant identity — from a single codebase, and what is required to onboard a new NRA tenant?

6. Status at MVP. Before AMA's Workflow engine is operational, what submission status and queue visibility does your solution provide out of the box, and how does this hand over to the Workflow engine once it is live?

7. AMA – vendor co-development. What information, documentation and support do you need from the AMA team to launch the MVP scope?

8. (Optional) Submission portal. How would your solution provide a submission portal for sponsors to submit regulatory requests? (AMA's initial scope is Market Authorization but expands beyond)

B5.3 Data Foundations and Integrations (RFP Section 5.2.7)

Vendors responding to this module are asked to address the following:

Proposed data architecture. Please propose a data architecture for AMA across foundations, master data, integrations and analytics. Provide a list of proposed solutions and a plan for integrating them across AMA's other systems.

Master data approach. How does your solution implement and govern master data across distributed environments?

Integration model. How does your solution support hybrid integration across NRAs with varying maturity levels?

Standards compliance. How does your solution align with SPOR, IDMP, and interoperability standards?

Scalability. How does your solution scale to a multi-country, continental deployment?

Data governance. How does your solution ensure data quality, stewardship, and auditability across the platform?

AI enablement. How does your solution(s) enable AMA to utilize AI in various aspects of their regulatory work? What areas should AMA focus on initially? Please provide examples.

Delivery sequencing and futureproofing. How will you sequence delivery across the MVP and subsequent phases, and how will you ensure that early design decisions support future expansion in both capability and volume?

Change management and adoption. How do you plan to support AMA in adopting data governance principles and practices? Describe your understanding of the scale of this effort, the responsibilities you expect AMA to carry, and the support you would provide.

Metadata management. How does your solution manage metadata, canonical models, semantic harmonization if applicable, etc?

Data sync. How will your solution handle ongoing data sync, for instance deduplication, data quality issues (particularly important to specific where the source data comes from)

B5.4 Enterprise Setup (RFP Section 5.3.8)

Vendors responding to this module are asked to address the following:

Cloud strategy. How does your solution support sovereign, multi-region cloud deployment aligned with AMA requirements?

Security model. How does your solution implement Zero Trust and protect sensitive regulatory data?

IAM approach. How does your solution integrate with federated identity and enforce access control? How will your solution centralize IAM across AMA systems with easily configurable roles for non-technical administrators?

ITSM Approach. How does your proposed solution support an ITSM platform and toolchain — including integration of service operations with cloud monitoring and security incident handling — and what role will the System Integrator and managed service partners play in day-to-day operations during the initial operating period?

Scalability and resilience. How does your solution ensure high availability and disaster recovery?

Productivity integration. How does your solution integrate with collaboration tools (e.g., M365) to support distributed users?

Gaps in enterprise setup. Have you identified any gaps in AMAs enterprise setup? How would you propose addressing them?

Disaster Recovery and resilience approach. Please describe your proposed disaster recovery architecture and deployment model, including:

- expected recovery time (RTO) and recovery point objectives (RPO)
- approach to data backup and recovery
- dependencies on cloud provider capabilities

Explain how your approach ensures resilience, continuity of operations, and alignment with AMA's sovereign and distributed operating model.

B5.5 Systems Integration (RFP Section 5.4.8)

These questions are the primary means by which AMA will understand the SI's capabilities. Vendors should answer each in their Technical Approach.

Multi-vendor orchestration & governance

VQ-4-1 Propose your governance and delivery-team structure, mapped to the workstreams, within AMA's fixed anchors (steering committee, focal points, decision rights), and the agreements and registers you would own.

VQ-4-2 Explain how your coordination model maintains single-point integration accountability whether a module vendor is your partner or is contracted independently by AMA, and how you coordinate, sequence and assure delivery in each case.

VQ-4-3 Describe how you will deliver or subcontract the Data and Enterprise foundations, the subcontractors you propose, and how you maintain single-point accountability across them.

Integration approach

VQ-4-4 Describe your approach to delivering the integration layer (iPaaS, API gateway, event mesh) and the eight critical-path integrations, including the standards and patterns you would apply.

VQ-4-5 Describe your repeatable integration pattern / playbook and how you would apply it to the AMRH and ECRES ad-hoc integrations, including how you plan and build where source-system readiness is uncertain.

VQ-4-6 Describe how your architecture and patterns scale to later-phase continental connectivity (NRA Integration Kit, REC and global-partner integrations) without rework.

VQ-4-7 Describe how you codify and hand over reusable patterns, standards and assets so AMA and future vendors can reuse them.

Delivery, discovery & risk

VQ-4-8 Describe how you would run the time-boxed discovery (Phase 0) to validate scope, confirm source-system readiness and firm the 2027 estimate at a gate, and what you would price separately for it.

VQ-4-9 Describe your delivery methodology and quality / stage gates, and how you assure timelines, budget and quality across multiple vendors and subcontractors.

Change management, adoption & run

VQ-4-10 Describe your change management, training and user-onboarding approach for both AMA staff and external applicants.

VQ-4-11 Describe your managed-services, hypercare and IT service-management model post-launch, and the service levels you would commit to.

Capability transfer & innovation

VQ-4-12 Describe how you will transfer knowledge and build AMA's internal capability, recognizing AMA's intent to retain a majority-internal team and grow toward advising NRA ICT teams.

VQ-4-13 Describe how your approach and target architecture support the future introduction of AI-assisted capabilities (e.g., assisted review, automated validation, signal detection, analytics).

Optional — partner-managed run (“SI run”)

VQ-4-14 (optional, non-binding). AMA is evaluating whether to operate the platform itself or engage a partner-managed run (“SI run”). As an optional item that is not part of the scored core award and does not commit AMA to procure it, describe your proposed managed-service model: scope (hosting, security operations/SOC, ITSM, application support), the operating and SLA model, the AMA-partner responsibility split, how it transitions to AMA's growing internal team, and indicative separate pricing. AMA reserves the right to take up, defer or decline this option.

B5.6 Sponsor and AMA Portal (RFP Section 5.5.2.5)

Vendors responding to this module are asked to answer the following (cross-referenced to Chapter 6 evaluation):

- 1. Extensibility.** How does your solution support modules as independently-deployable extensions (extension contract/SDK, micro-front-end or module federation) without rebuilding the core? Provide a reference where multiple modules - or third parties - extended your platform.
- 2. No-code configuration.** How would a non-technical authority user change a business process through an admin UI so that regulatory configuration update without code or redeployment? Demonstrate it, including forms and decision rules; illustrate conformity with AMA's outlined integration model.
- 3. Data & cross-module correlation.** How are configurable data models and forms maintained without code; how does the platform consume master data and publish transactional data and events to an external data fabric (no silo); and how do records carry canonical identifiers so one product can be tracked across modules?
- 4. Multi-tenancy.** How does your platform provide tenant isolation, per-tenant configuration/branding, and per-tenant federated identity from a single codebase, and what is required to activate a new (NRA) tenant?
- 5. Resilience / fault isolation.** How are module-surface faults isolated so that one failing module does not bring down the Portal?
- 6. Openness & exit.** What APIs, data-export, and contract-versioning guarantees ensure AMA can extend, integrate, and ultimately exit without re-platforming? (SO-5.5.2-11)
- 7. SI collaboration & proactive development.** AMA is building multiple systems in parallel where the data used to inform the portal may be sparse or not yet developed. How will you work with the SI to proactively develop features in advance of potentially dependent capabilities? Provide an example where you've completed a development like this?

B5.7 Workflow Engine (RFP Section 5.5.3.4)

Vendors responding to this module are asked to answer the following:

Workflow design principles. Please describe how your solution adheres to AMA's workflow design principles?

Case model. How would your solution configure and manage Phase 2 AMA case types, including Market Authorization applications including regulatory correspondence (e.g., list-of-questions) response cycles?

Centralized Automation. How might your solution support centralized rules-based automation within these regulatory workflows (e.g., automatic submission routing, re-inspection triggering)?

Linked and dependent cases. How does your solution support linked cases or sub-cases, such as an inspection or a regulatory correspondence (e.g., list-of-questions) cycle connected to a parent Market Authorization case?

Integration and event management. How would your solution read and write from an enterprise event mesh? How do you envision your solution integrating with the AMA portal?

(Optional) How could your solution support configuration through the AMA portal instead of a dedicated workflow interface? Please assess technical feasibility, options and potential risks.

Audit and reporting. What audit-log export options and configurable dashboards are available for case status, clock status, overdue items, throughput, and workload?

Data workflows. How does your solution support Master Data Management focused workflows? Please provide real regulatory examples.

Multi-tenant / NRA-tenant configurability. How does your solution isolate process, configuration and data per tenant/authority, and how would a future NRA tenant configure its own workflows, rules, timelines and clock model (for example, adding a review cycle for a particular NRA) without affecting other tenants or requiring code changes?

B5.8 Market Authorization and Inspections

Market Authorization (RFP Section 5.5.4.3)

1. Assembly approach. Describe how your solution assembles the MA module from the shared foundations (portal, eCTD, workflow engine, data, IAM): which components you provide, which you integrate with, and how you avoid duplicating shared capabilities.

2. NRA reliance and controlled sharing. Describe how your solution supports controlled sharing of AMA assessment outputs and dossiers with NRAs, including per-NRA template/format conversion, sponsor-controlled disclosure, redaction of confidential information, multi-language handling, and tracking of NRA reliance. Indicate which capabilities are available now versus roadmap.

3. Configuration and AMA ownership. Describe how MA workflows, business rules, templates and timelines are configured, and how AMA administrators own and govern changes after go-live without vendor development.

4. AI-assisted capabilities (human in the lead). Describe any AI-assisted capabilities your solution offers across the MA process - for example, submission triage, literature-search assistance, translation across AMA languages (English, French, Portuguese, Arabic), and assessment-report summarization - and how these operate under responsible-AI principles with human review and accountability. Indicate which capabilities are available now versus roadmap.

Inspections (RFP Section 5.5.9.3)

1. Inspection lifecycle. Describe how your solution supports the inspection lifecycle (planning, scheduling, on-site execution, reporting and CAPA follow-up), including mobile and offline-capable access for inspectors.

2. Regulatory data links. Describe how inspection data links to MA records and SPOR organization/site data, indicating availability today versus roadmap.

B5.9 Context Modules (RFP Section Section 5.5.5–5.5.10) – For vendors submitting proposals for the Portal and Workflow engine

Clinical Trials (RFP Section 5.5.6.3)

1. Lifecycle support. Describe how your solution may scale to support the clinical-trials lifecycle - application, parallel scientific and ethics review, amendments, and safety reporting during conduct - and how it reuses the shared foundations rather than introducing a separate stack.

2. Standards and transparency. Describe future support for clinical-trial standards and transparency (ICH E6(R3)/GCP, CDISC, and public trial registries such as WHO ICTRP / PACTR) and integration with pharmacovigilance (E2B) and trial-registry systems, indicating what is available today versus roadmap.

Lifecycle Management (RFP Section 5.5.7.3)

1 High-volume lifecycle. Describe how your solution manages high-volume, low-complexity lifecycle submissions (variations and renewals) linked to a parent MA, including variation-category-driven timelines and full change history.

Post-Market Surveillance (RFP Section 5.5.8.3)

1. Signal management. Describe how your solution supports signal management (detection, validation, assessment, escalation) and event-driven processing of safety data, and integration with pharmacovigilance systems such as AfriVigilance and the E2B standard.

2. Cross-border exchange. Describe how your solution supports cross-border signal detection and near-real-time bidirectional exchange with NRA systems, indicating availability today versus roadmap.

Lab Management (RFP Section 5.5.10.3)

1. Testing & samples. Describe how your solution supports laboratory testing coordination and sample/result management (LIMS-style), and how testing is initiated from and returned to regulatory workflows such as MA and Inspections.

2. Laboratory integration. Describe any integration with external or contract laboratories and the management of test methods and results, indicating availability today versus roadmap.

B6 Work Plan and Timeline

Vendors shall provide a detailed implementation plan covering:

- Design
- Build
- Testing
- Deployment

Milestones

The plan shall include milestones aligned with:

- MVP delivery (MVP scope)
- Phase 1 scope delivery
- Knowledge transfer, transition, and target-state preparedness

Dependencies, Assumptions and Open Questions

Vendors shall explicitly list all dependencies, assumptions and open questions that could affect the proposed timeline.

Given AMA's delivery model, vendors should consider: phased rollout, parallel workstreams, and incremental scaling in their plan.

Vendors are encouraged to present the work plan in a visual format (Gantt chart or equivalent), attached as a named exhibit.

B7 Staffing and Key Personnel

Vendors shall provide:

- Proposed team structure and organizational chart
- Roles and responsibilities for each team member

- Key personnel profiles (CVs), including relevant experience
- Staffing allocation across delivery plan phases (FTE by phase)

Given AMA's limited internal capacity, vendors must clearly describe: (a) the responsibility split between vendor, AMA, and any systems integrator; and (b) their approach to transition and knowledge transfer to AMA staff.

B8 Risks, Limitations, Assumptions and Dependencies

- Known constraints or product limitations relevant to AMA scope
- External dependencies (third-party licenses, infrastructure, data)
- Scalability risks and proposed mitigations
- Timeline risks specific to the MVP milestone (Jan 2027 MVP go-live)

B9 Deployment Model and Pricing

- Hosting model: SaaS / PaaS / on-premises / hybrid — specify
- Data residency: primary and failover region(s)
- Multi-tenancy approach and tenant isolation model
- Upgrade and release management process

Price this capability in Appendix D. Commercial Pricing Register. Pricing shall not be restated in this Appendix B.

Vendors shall break down pricing by delivery phase, covering implementation, staffing and ongoing commercial support (including licensing, maintenance and scaling considerations).

B10 Exceptions and Conflicts

Vendors shall explicitly disclose any of the following. Transparency in this section is critical for evaluation — undisclosed exceptions or conflicts discovered post-submission may result in disqualification.

Category	Description	Impact / Proposed Alternative
Deviations from requirements		
Assumptions impacting delivery		
Potential conflicts of interest		
Limitations or dependencies		
[Add row as needed]		

If no exceptions exist, the vendor shall state: “No exceptions — vendor confirms full compliance with all RFP requirements and terms.”

Appendix D - AMA Requirements Catalogue

See attached MS Excel sheet

Appendix E - Bid Submission Form (Technical Proposal)

To: The African Medicines Agency (AMA), through Garnet Partners Ltd.

Having examined the Request for Proposal, we, the undersigned, offer to provide the services described herein for the component(s) indicated below, in accordance with the RFP and its terms. This proposal is valid for ninety (90) days from the submission deadline.

Field	Bidder's response
Legal name of firm	
Country of incorporation / registration no.	
Registered address	
Authorized representative (name and title)	
Email / telephone	
Component(s) bid for	Component 1 / 2 / 3 / 4 / 5 (circle / list)
Bidding as	Single entity / Prime with sub-contractors / Consortium
Proposal validity	90 days from submission deadline

Authorized signature: _____ Date: _____

Appendix F - Financial Proposal Submission Form and Commercial Pricing Template

All prices shall be quoted in United States Dollars (USD), on a fixed-price basis, and shall separate Phase 1 (MVP) and Phase 2, consistent with Section 6.6. The financial proposal shall be submitted as a separate document.

See attached Commercial Pricing Register in MS Excel sheet

Authorized signature: _____ Date: _____

Appendix G - Declaration of No Conflict of Interest and No Debarment

We declare that: (i) we have no actual or potential conflict of interest in relation to this assignment; (ii) we are not subject to any active debarment or suspension by the African Union, the United Nations, the World Bank, or any equivalent authority; and (iii) all information provided in our proposal is true and accurate. We undertake to disclose promptly any change to this position.

Field	Detail
Legal name of firm	
Authorized representative (name and title)	
Signature	
Date	

Appendix H - Reference Project Form (complete one per reference; minimum two)

Field	Detail
Client / organization	
Country/region	
Contactable referee (name, title, email, phone)	
Description of Services Delivered/Scope	
Scale and complexity	
Component relevance (1-5)	
Contract value (USD)	
Start and end dates	
Health or medicines-regulation sector (Y/N)	

Appendix I - Key Personnel CV Summary Template (one per proposed expert)

Field	Detail
Full name	
Proposed role on the assignment	
Academic qualifications (certified copies attached: Y/N)	
Professional certifications (certified copies attached: Y/N)	
Years of relevant experience	
Summary of relevant assignments	
Committed availability (period / % time)	

Appendix J - Statement of Availability

We confirm that the key personnel named in our proposal are available to be engaged for the assignment for the periods indicated, and that we will not substitute them without the prior written approval of AMA.

Expert name	Proposed role	Confirmed availability (dates / % time)	Signature

Appendix K - Consortium / Joint Venture Declaration

Where bidding as a consortium or joint venture, complete the following and attach the Joint Venture / Association Agreement identifying the lead (prime) firm, which will be AMA's primary contractual counterparty.

Field	Detail
Lead (prime) firm	
Consortium / JV members	
Role and scope of each member	
JV / Association Agreement attached (Y/N)	