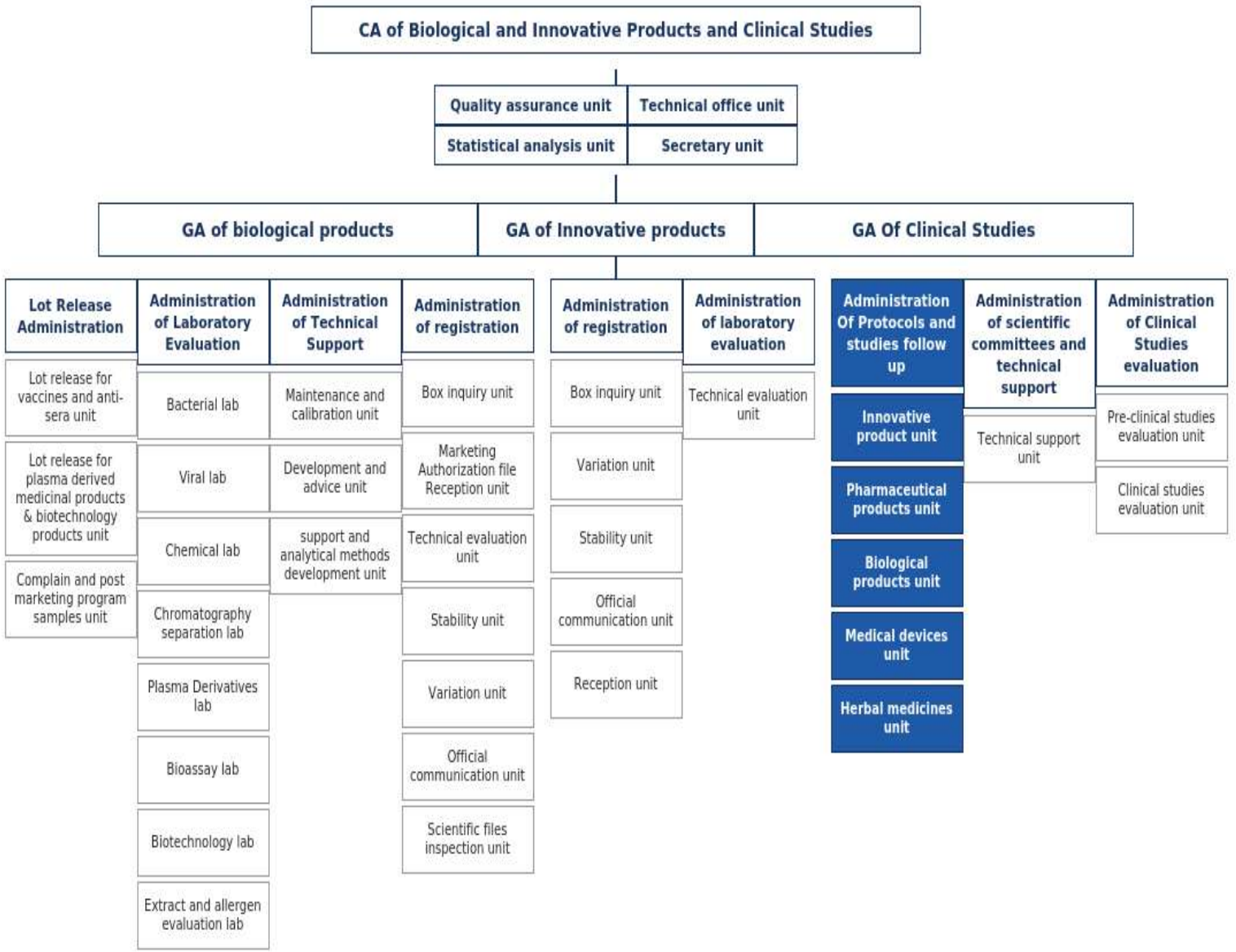
Protocols and Studies Follow-up Administration-
General Administration of Clinical Trials–
Activity Report 2023-2025

Agenda

BIOINN ORGANOGRAM



Protocols and Studies Follow-up Administration- General Administration of Clinical Trials– OVERVIEW

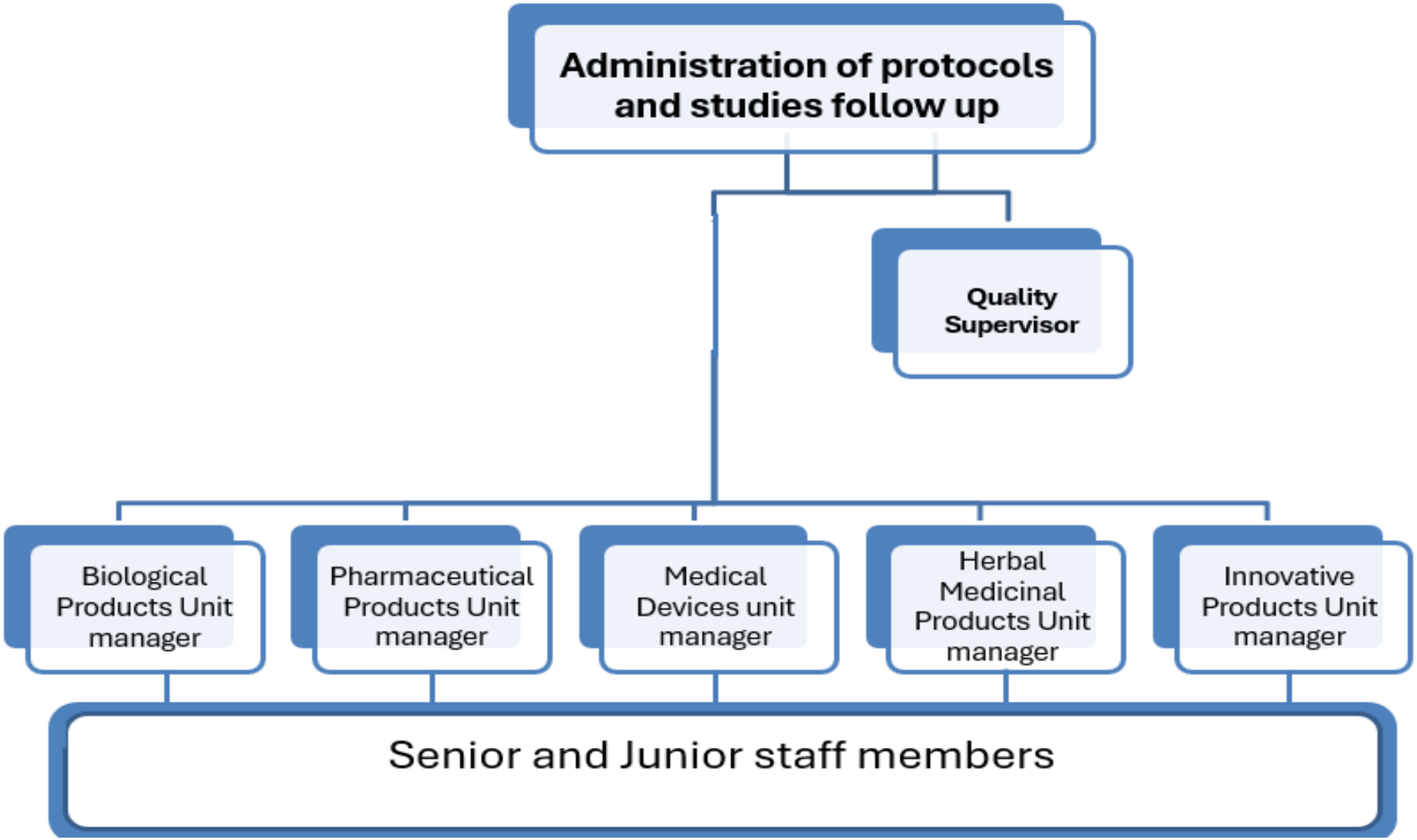
The Protocols and Studies Follow-up Administration, operating under the General Administration of Clinical Trials (GA of CT) at the Egyptian Drug Authority (EDA), is responsible for the regulatory oversight and follow-up of clinical trial applications and approved clinical studies throughout their lifecycle. The administration ensures that clinical trials are conducted in accordance with applicable national regulations, Good Clinical Practice (GCP) principles, ethical standards, and relevant international guidelines.

The administration implements its responsibilities through the evaluation of preclinical and/or previous clinical studies results for biological, pharmaceutical, herbal medicine, and innovative investigational medicinal products as well as medical devices; evaluation of the submitted research plan (protocol) for clinical medical research in all its phases and/or its amendments, in order to issue a decision (approval or refusal) to conduct clinical medical research.

Furthermore, the administration receives periodic progress follow-up and safety reports during the study and conducts GCP inspections on all entities related to the clinical medical research to ensure adherence to the principles of Good Clinical Practice. In addition, the administration is responsible for receiving and evaluating the interim and the final clinical study reports and overseeing that the study is completed within the clinical research sites.

Through its activities, the administration contributes to safeguarding the rights, safety, and well-being of clinical trial participants, ensuring data integrity and reliability, and supporting the efficient and transparent regulation of clinical research conducted under the oversight of the Egyptian Drug Authority.

Protocols and Studies Follow-up Administration-ORGANOGRAM



Responsibilities of Protocols And Studies Follow-up Administration

The Administration and its units are responsible for all tasks related to the supervision and following-up of clinical studies that are conducted in the Arab Republic of Egypt and evaluating their results through:

1. Evaluation of preclinical and/or previous clinical studies results for biological, pharmaceutical, herbal medicine and innovative investigational medicinal products as well as medical devices.
2. Evaluation of the submitted clinical medical research plan (protocol) for clinical medical research in all its phases and/or its amendments, in order to issue a decision (approval or refusal) to conduct the clinical medical research.
3. Receives periodic progress follow-up and safety reports during the study.
4. Conducts GCP inspection on all entities related to the clinical medical research to ensure the adherence to the principles of Good Clinical Practice.
5. Receiving and evaluating the interim and the final clinical study reports and ensuring that the study is completed within the clinical research sites.

Clinical Trials Portfolio – Key Figures (2023)

EDA Clinical Trials Registry · Trials submitted in 2023

17
Total Registered Trials

47
2023 Amendments

2
Currently Recruiting
Active enrollment

2
Completed Trials
Full study completion

2
Early Terminated
By sponsor

6
Withdrawn Trials
By sponsor / regulatory

1
Recruitment Completion
Enrollment closed

2
Suspended Trials
Temporary hold

1
Refused / Cancelled
Not authorized

1
Terminated
By EDA / sponsor

Trials by IMP Type

Biological — 5 trials

Pharmaceutical — 8 trials

Innovative — 4 trials

Clinical Trials Portfolio – Key Figures (2024)

EDA Clinical Trials Registry · Trials submitted in 2024

47
2024 Amendments
Peak amendment year

9
Total Registered Trials
Submitted in 2024

5
Withdrawn Trials
By sponsor / regulatory

2
Recruitment Completion
Enrollment closed

2
Refused / Cancelled
Not authorized

Trials by IMP Type

Biological — 3 trials

Pharmaceutical — 4 trials

Herbal — 2 trials

Clinical Trials Portfolio – Key Figures (2025)

EDA Clinical Trials Registry · Trials submitted in 2025

15
Total Registered Trials
Submitted in 2025

20
2025 Amendments
Partial-year data

9
Withdrawn Trials
By sponsor / regulatory

3
Approved – Ongoing
No status update yet

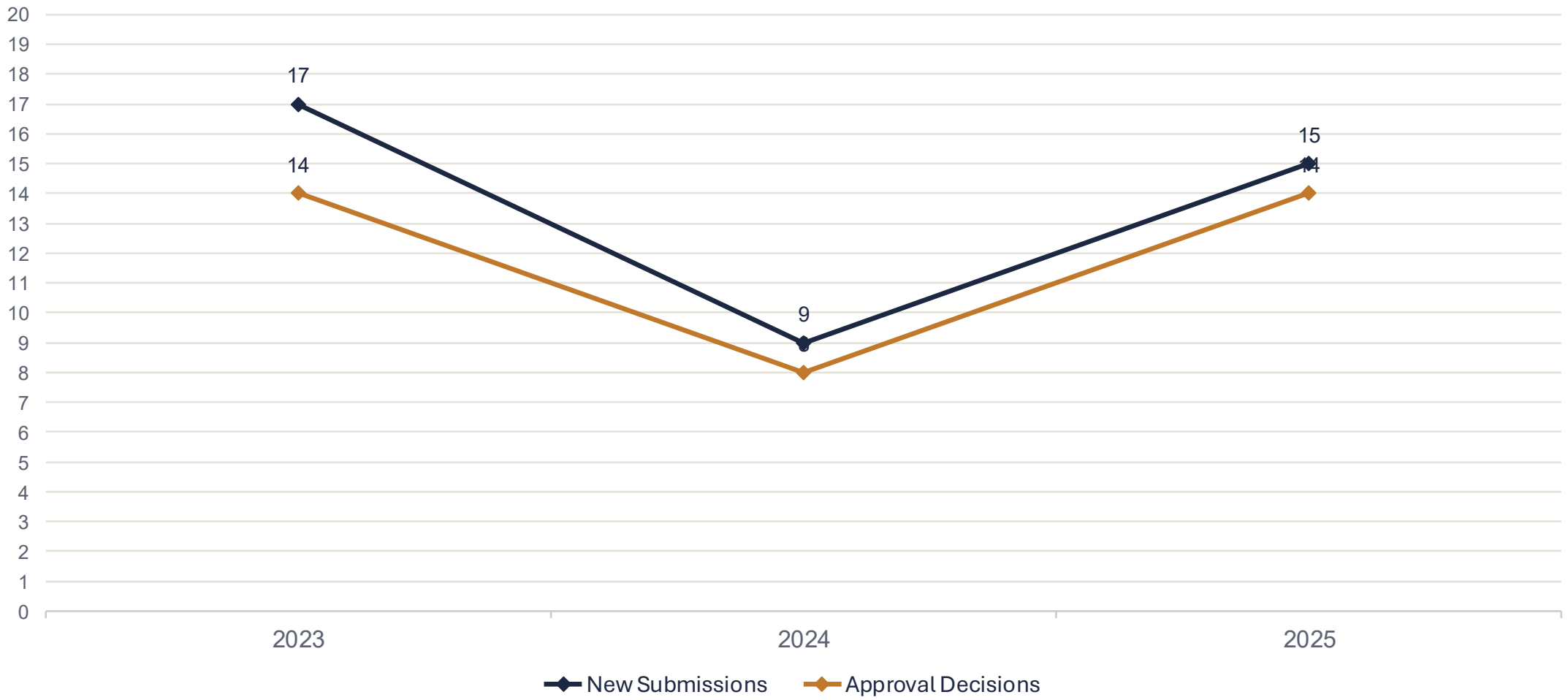
2
Currently Recruiting
Active enrollment

1
Refused / Cancelled
Not authorized

Trials by IMP Type

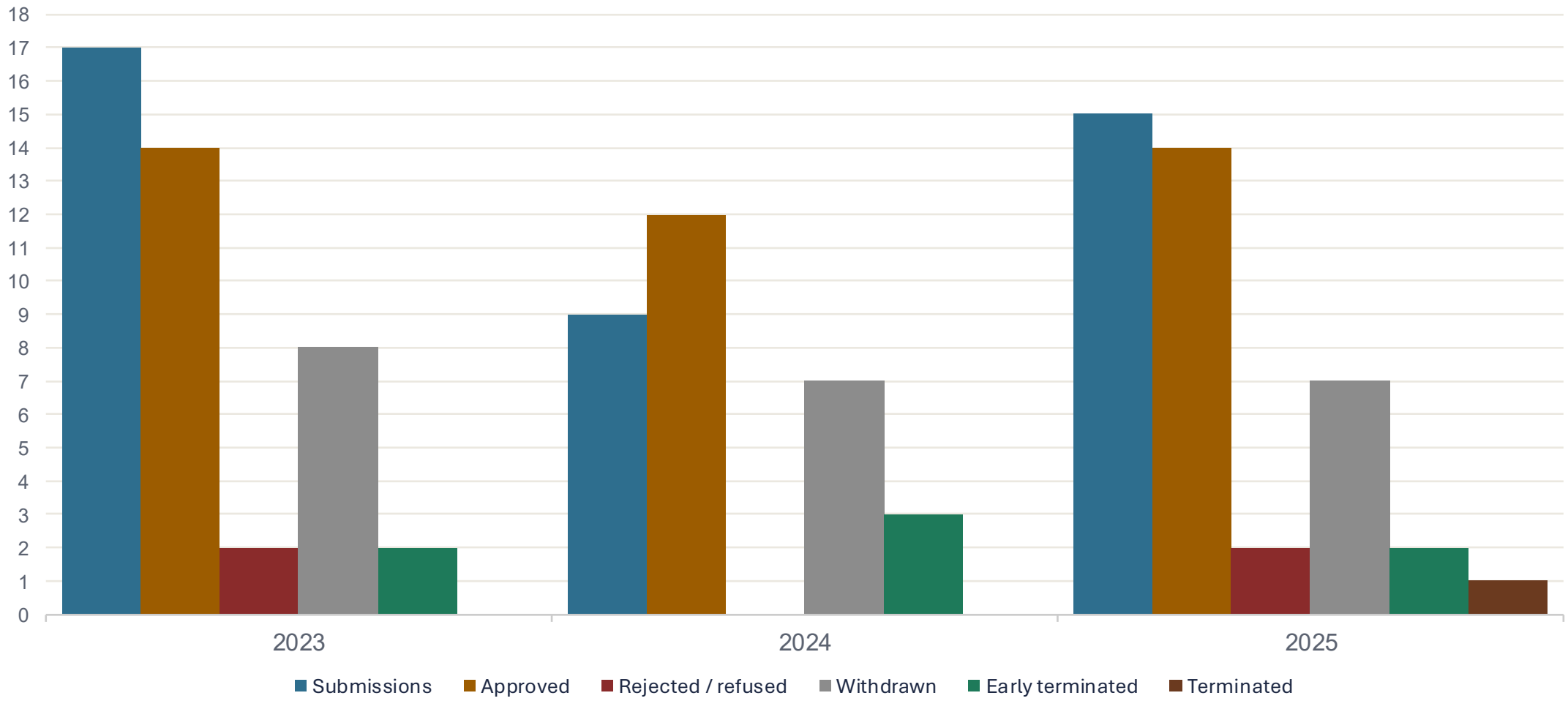
- **Biological — 6 trials**
- **Pharmaceutical — 8 trials**
- **Innovative — 1 trial**

Submission & Approval Trends (2023–2025)



Annual new clinical trial submissions and EDA approval decisions recorded in the CT Registry (2023–2025).

Submission & Approval Trends (2023–2025)



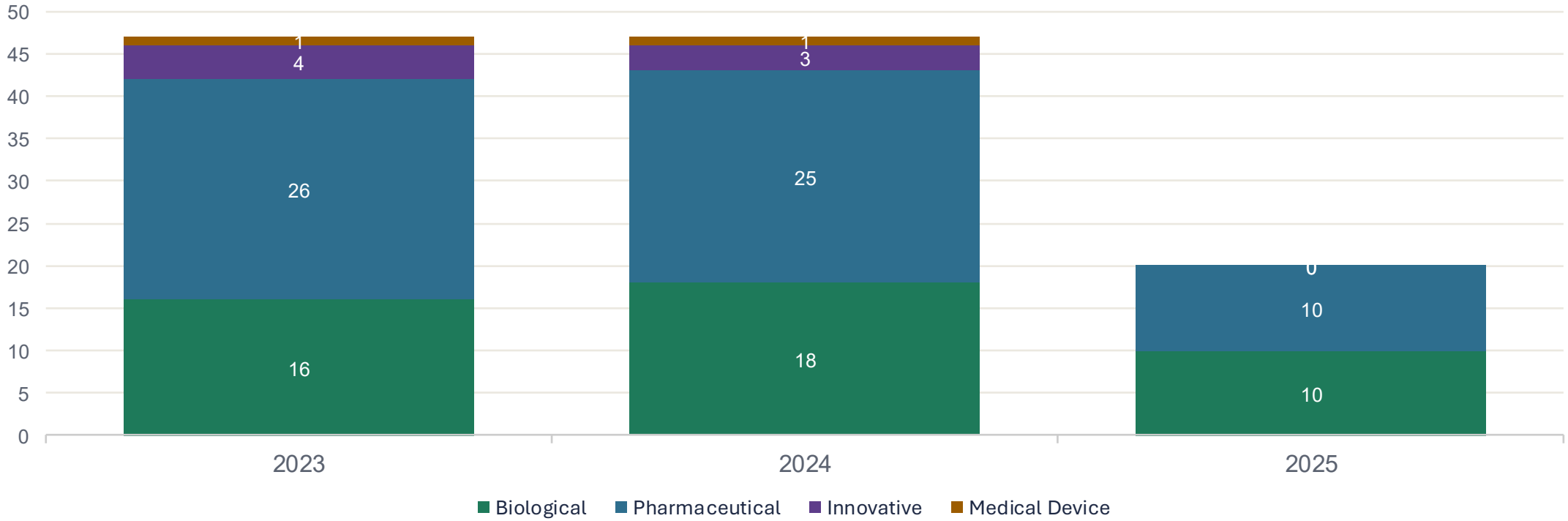
Annual new clinical trial submissions and EDA regulatory decisions recorded in the CT Registry (2023–2025).

Substantial Amendments – Key Figures & Trend (2023–2025)

Source: Revised List of Protocols · Amendment receipt dates

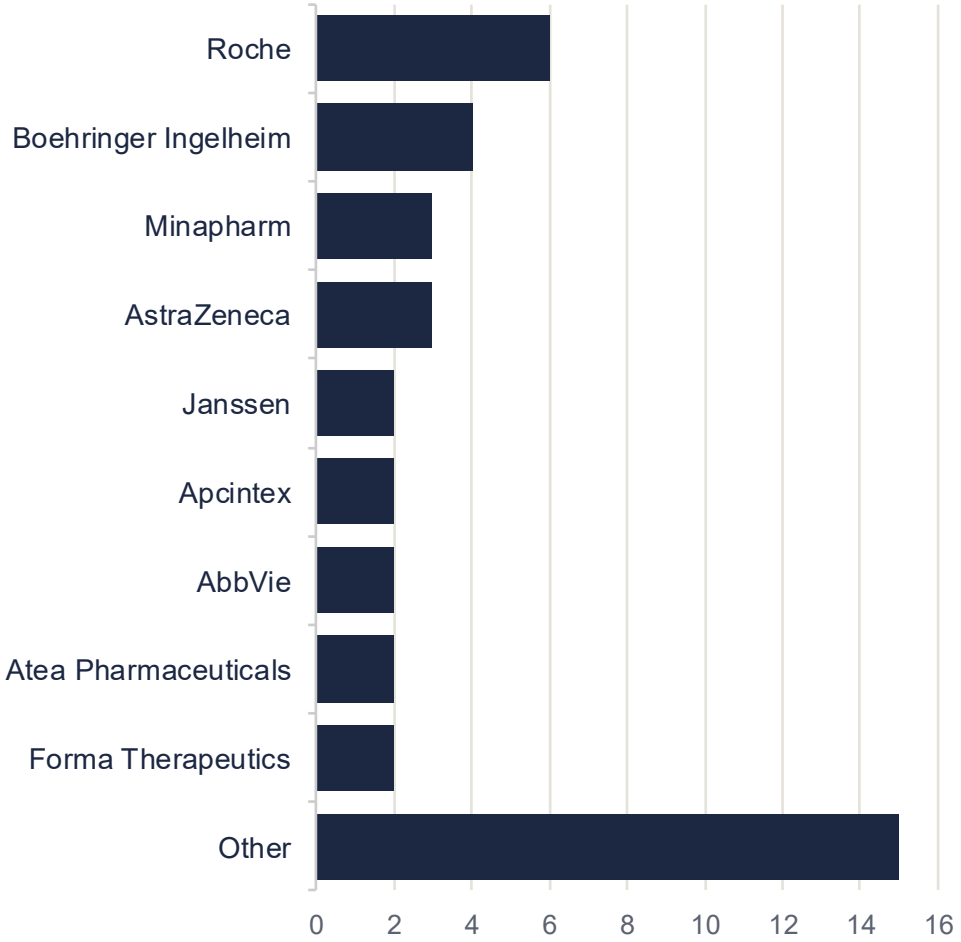
114	47	47	20
Total Amendments	**2023 Amendments**	**2024 Amendments**	**2025 Amendments**
2023–2025	Biological + Pharma led	Peak amendment year	Partial-year data

Substantial Amendments by Category & Year

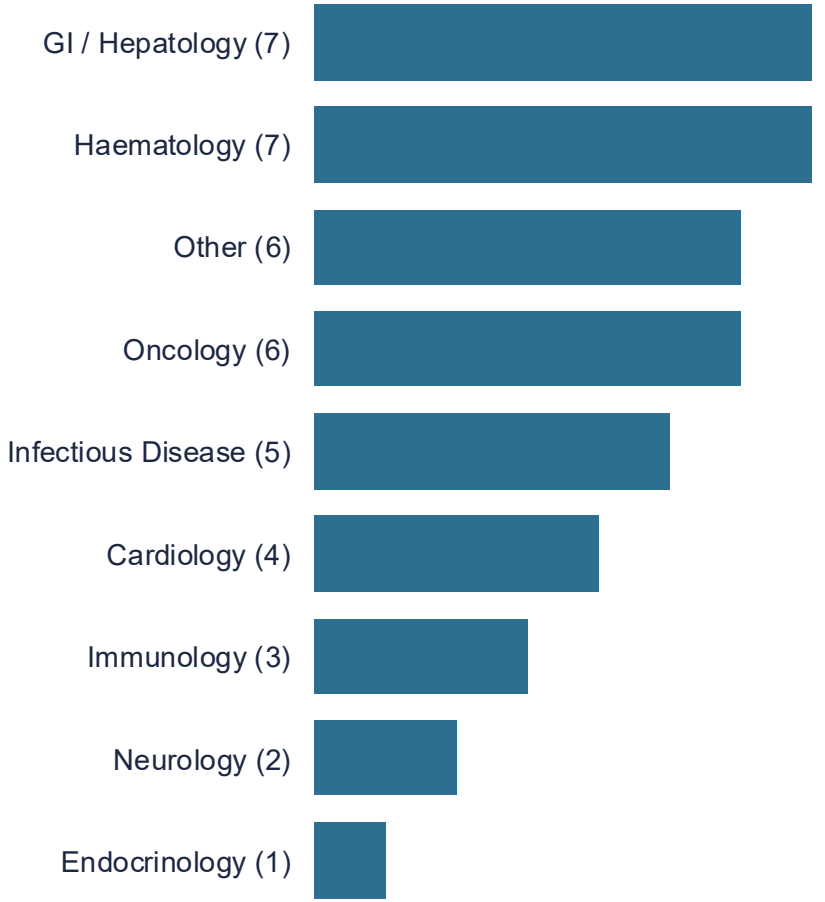


Sponsor Landscape & Therapeutic Focus

Sponsor (2023–2025)



Therapeutic Areas (2023–2025)



GCP Inspections – Key Figures (2023)

26

Total Inspections

24

Comply

GCP compliant outcome

1

Suspended

Subsequent follow-up

1

Terminated

Regulatory enforcement action

3 **Outside Egypt** (International site inspections)

14

Phase III Trials

Dominant phase category

4

Phase I / BE Studies

Incl. bioequivalence studies

11

Sponsors Engaged

Multinational & local sponsors

GCP Inspections – Key Figures (2024)

39

Total Inspections

37

Comply

GCP compliant outcome

1

Suspended – Resumed

Regulatory enforcement action

1

Suspended

Subsequent follow-up

13

Phase III Trials

Dominant phase category

20

Phase I / BE Studies

Incl. bioequivalence studies

26

Sponsors Engaged

Multinational & local sponsors

GCP Inspections – Key Figures (2025)

60

Total Inspections

58

Comply

GCP compliant outcome

1

Suspended – Resumed

Regulatory enforcement action

1

Suspended

Subsequent follow-up

24

Phase III Trials

Dominant phase category

29

Phase I / BE Studies

Incl. bioequivalence studies

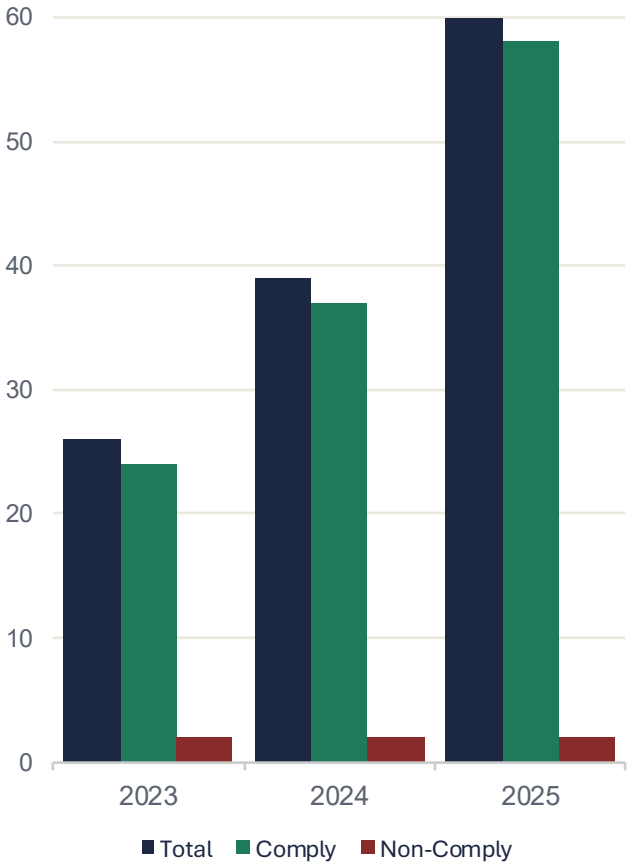
36

Sponsors Engaged

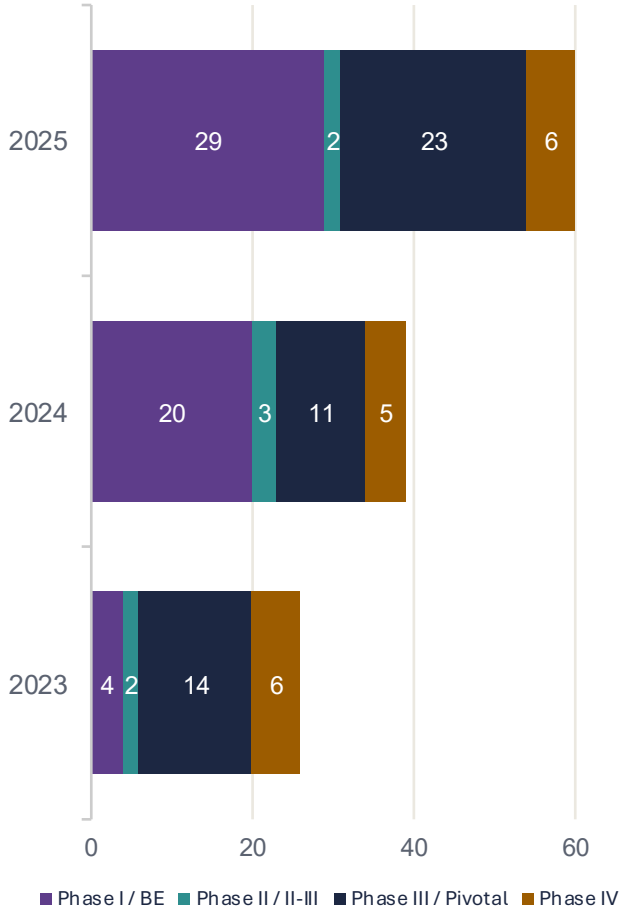
Multinational & local sponsors

Inspection Activity – Statistical Overview (2023–2025)

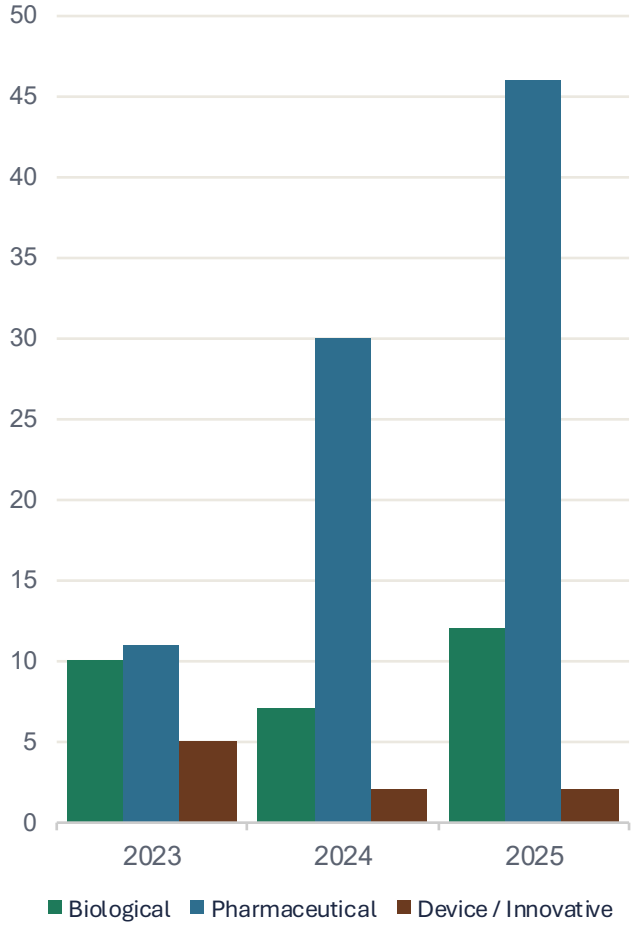
Total Inspections vs Outcome



Phase Distribution by Year

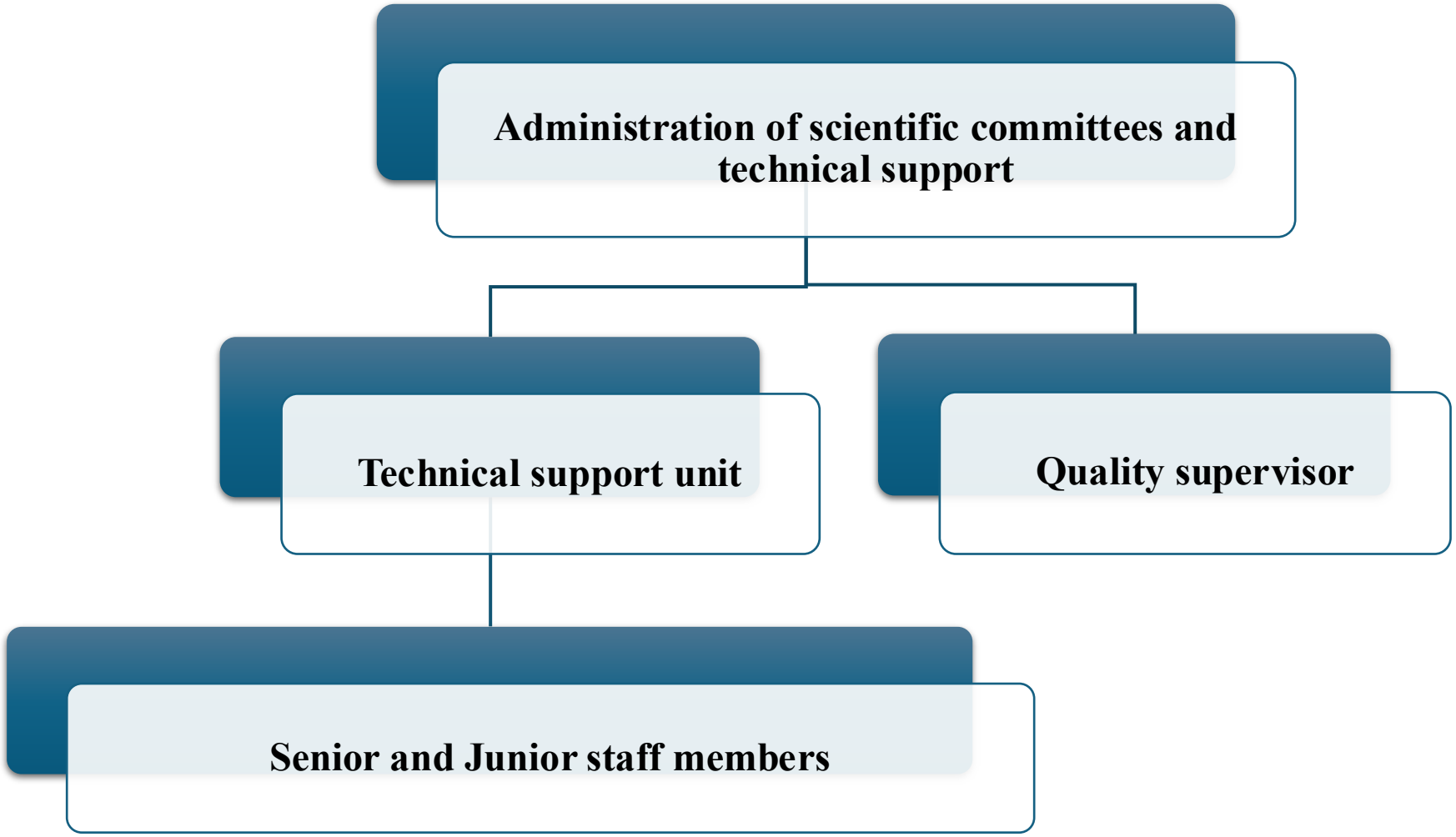


IMP Type Distribution by Year



Administration of Scientific Committees and Technical Support
General Administration of Clinical Trials
activity Report 2023-2025

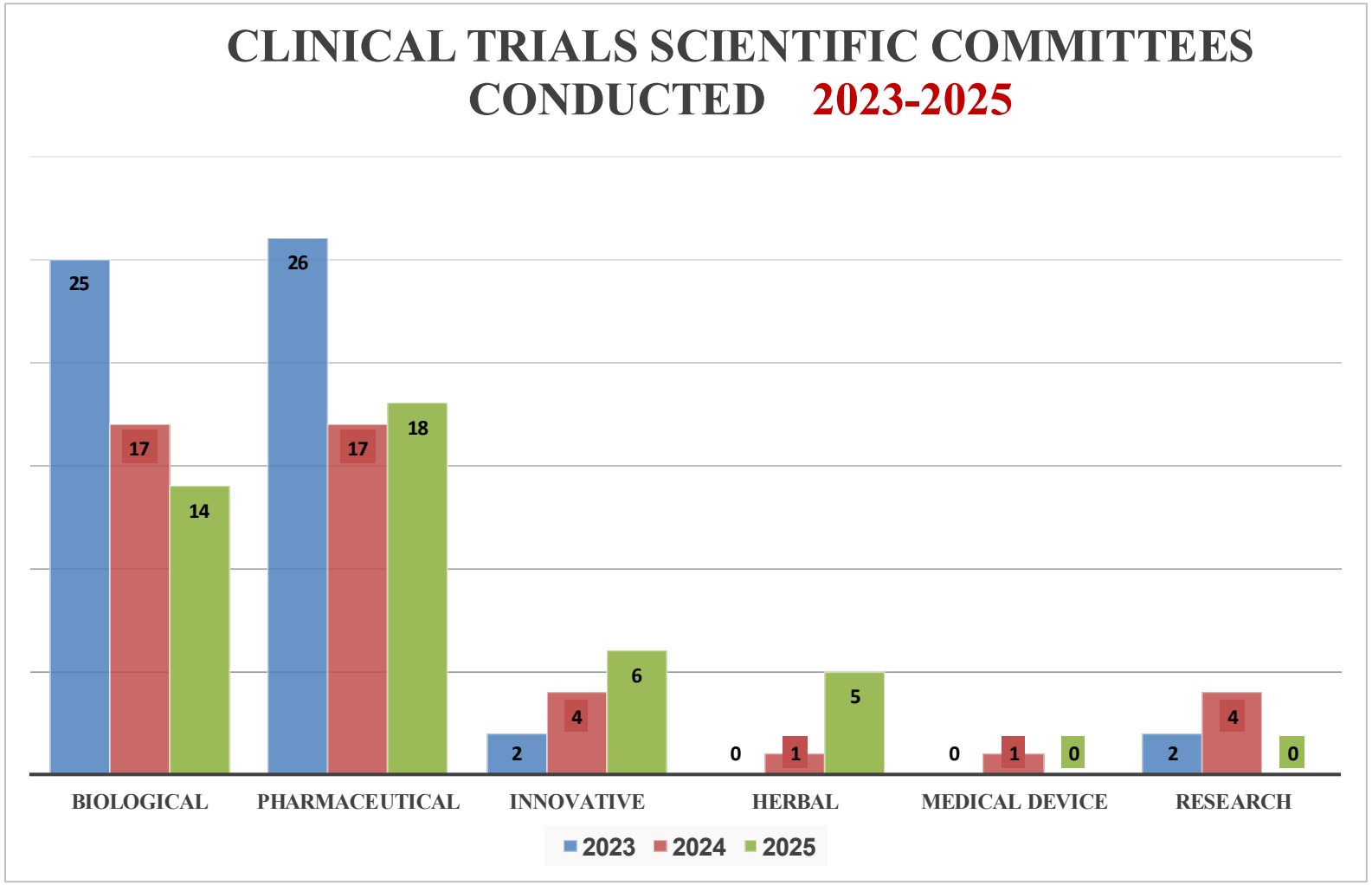
Scientific Committees and Technical Support Administration-
ORGANOGRAM

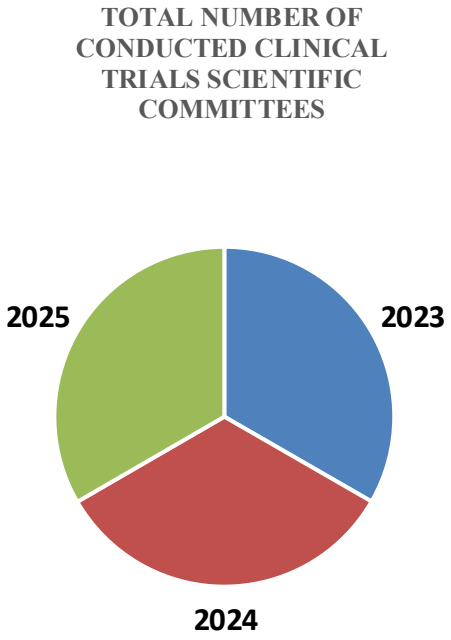


Responsibilities of Scientific Committees and Technical Support Administration

Providing Technical support assistance through	EDA's advisory scientific committee for preclinical and clinical studies evaluation.	Others
1. Receiving technical support requests from applicant for evaluation and organizing and conducting the required support with the help of other relevant administrations if necessary. 2. Giving the scientific advice and technical support data regarding preclinical and clinical trials requested by EDA internal administrations.	1. Expressing the scientific decision of the pre-clinical and clinical research results with raising recommendation regarding starting the next developmental stage or not. 2. Expressing the scientific decision in the follow-up reports and the adverse events reports and complications with raising recommendations regarding suspend or terminate the clinical trial(s) if needed. 3. Provide the scientific consultation of the preclinical and clinical trials whenever necessary. 4. Other roles may be added upon request.	1. Follow-up and prepare drafts for updating the regulating decrees that regulates clinical and pre- clinical studies in accordance with the international standards/ national regulations for good clinical practice. 2. Updating the local guidelines used in evaluating preclinical & clinical studies in accordance with the international standards/national regulations. 3. Incorporating in the public consultation of international guidelines.

Clinical Trials Scientific Committees Conducted 2023-2025



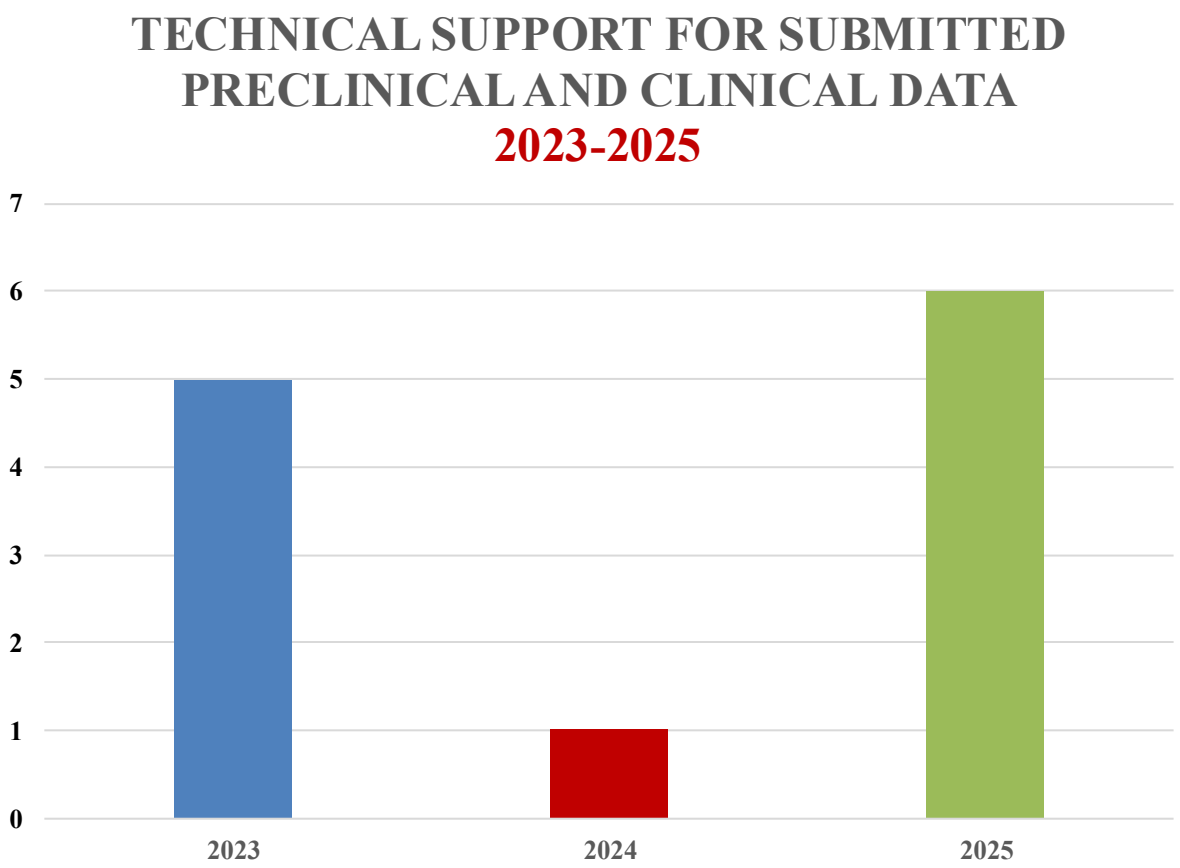


Data illustrates committee activity that was conducted between 2023-2025. Overall, while biological and pharmaceutical trials dominated committee activity across all three years, both categories revealed declines from their 2023 peaks. Meanwhile, smaller categories such as innovative and herbal trials show a gradual upward trajectory, potentially signalling a diversification of research focus over the observed period.

Technical Support for Submitted Preclinical and Clinical Data 2023-2025

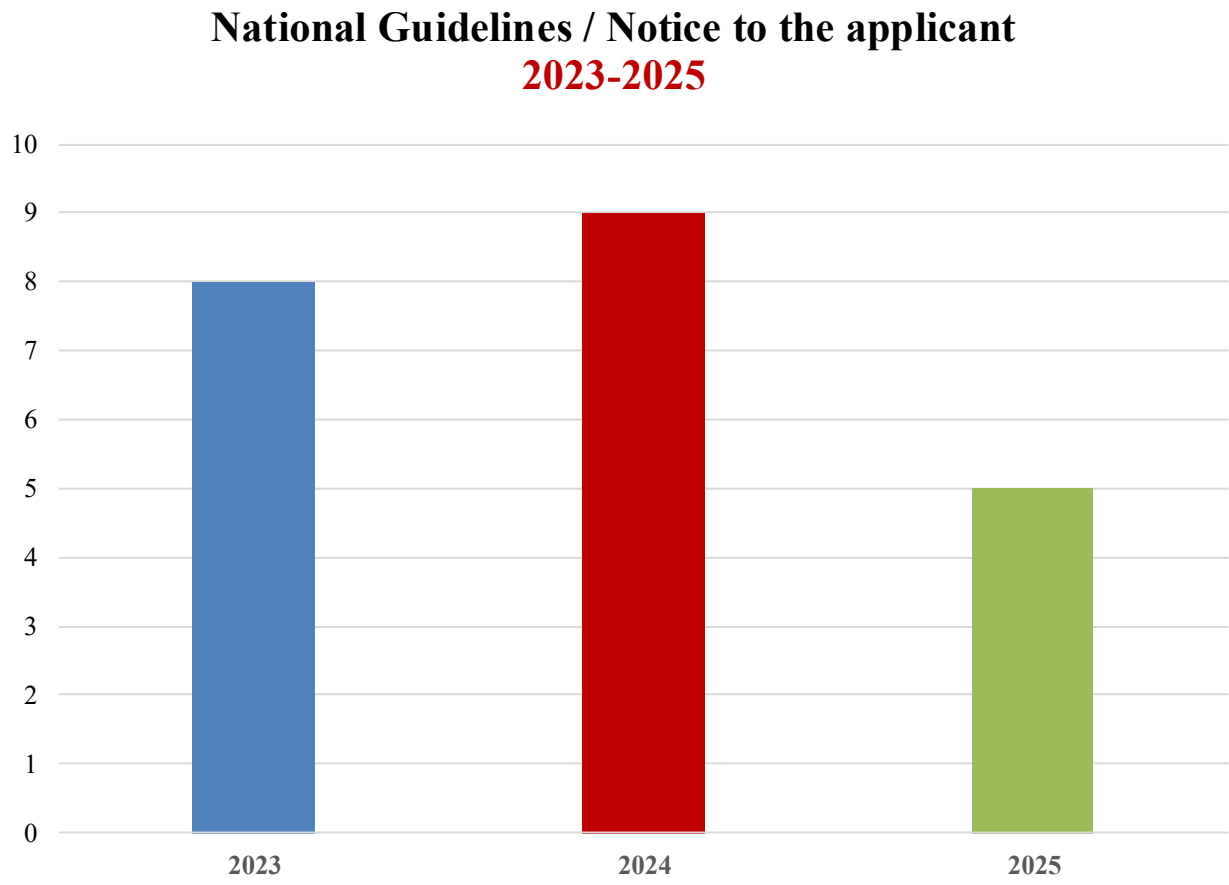
Technical support provided for submitted preclinical and clinical data or dossiers showed a fluctuating pattern over the reviewed period.

- **In 2023, 5 technical support dossiers were assessed, which fell sharply to just 1 in 2024 (a decline of 80 %). Activity then rebounded substantially in 2025, reaching 6 dossiers (the highest figure across the three-year span).**



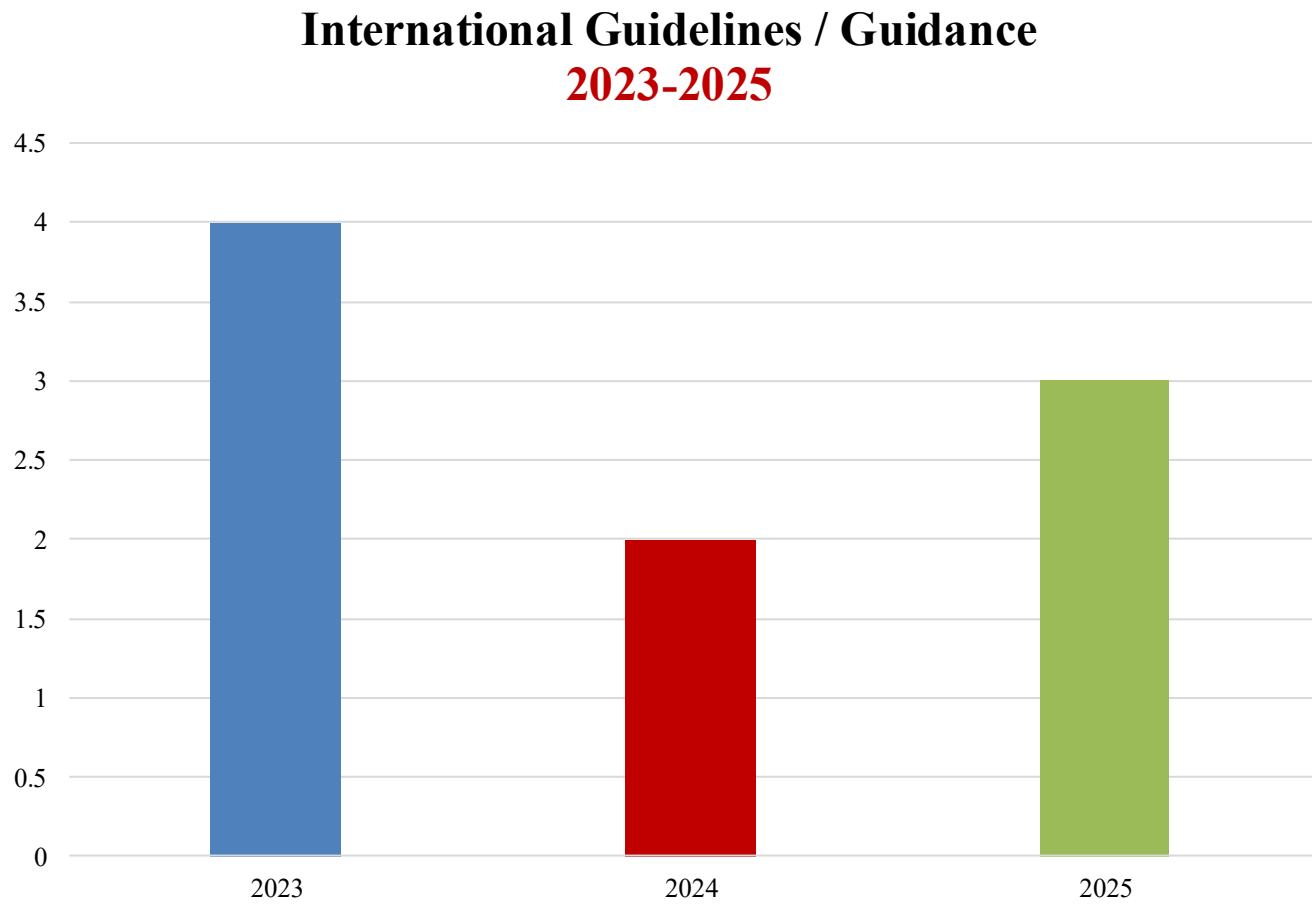
National Guidelines / Notice to Applicant 2023- 2025

The number of national guidelines and notices issued to applicants remained relatively high throughout 2023 and 2024 before declining in 2025. Specifically, 8 were recorded in 2023, rising slightly to 9 in 2024, before dropping to 5 in 2025 (a decrease of approximately 44% from the 2024 peak).



International Guidelines / Guidance 2023- 2025

International guidelines/guidance Clinical Trials team has participated in their consultations between 2023 and 2025 followed a downward then upward trend. A total of 4 guidelines were recorded in 2023, decreasing to 2 in 2024, before rising again to 3 in 2025.



Accreditation/Recognition/ Membership

WHO benchmarking

- In March 2022, the World Health Organization (WHO) designated Egypt's National Regulatory Authority (NRA) for vaccines as Maturity Level 3 (ML-3) — the second-highest tier in WHO's Global Benchmarking Tool (GBT) classification — making Egypt's NRA the first to reach ML-3 for vaccine regulation in the Eastern Mediterranean Region and the ninth at global level. The formal benchmarking mission was carried out by a WHO-led team of international assessors between February and March 2022, evaluating regulatory functions against more than 250 indicators.

- In September 2024, EDA extended this achievement by attaining ML3 for medicines regulation as well, following a rigorous benchmarking process finalized in November 2024, achieved through close collaboration with WHO's regional office for the Eastern Mediterranean Region and coordination by the WHO country office in Egypt. With this, Egypt became the first country in Africa to achieve ML3 for both medicines and vaccines regulation.

WHO GCTF

World Health Organization

EDA Active Participant & Contributor

WHO Global Clinical Trials Forum (GCTF)

EGYPTIAN DRUG AUTHORITY JOINED Global Clinical Trials Forum (GCTF)

What is the WHO GCTF?

The WHO Global Clinical Trials Forum is the premier international platform for regulatory authorities, national ethics committees, and key stakeholders to exchange experience, align standards, and advance the global clinical trials ecosystem. It addresses CT oversight, participant protection, and regulatory harmonisation worldwide.

EDA's Role & Engagement

EDA participates as an active national regulatory authority member, contributing Egyptian regulatory perspectives to global discussions on GCP harmonisation, clinical trial oversight frameworks, and regulatory capacity strengthening across low- and middle-income country settings.

Key Activities & Contributions

- Contribution to strengthening clinical trial ecosystem and implementation CT global action plan.
- Exchange of best practices on CT registration, informed consent and Useful resources with other members.
- Collaboration with WHO on aligning Egypt's CT regulatory framework supporting WHA75.8 implementation

Strategic Impact for Egypt

EDA's engagement positions Egypt as a regional leader in clinical trial regulation and directly strengthens the credibility of Egyptian clinical sites with international sponsors, CROs, and WHO. It also ensures Egyptian regulatory developments are reflected in emerging global standards.

International Achievements

ICH M15 M18 E22

International Council for Harmonisation

EDA Topic Leader & EWG Member

Egyptian Drug Authority

ICH M15, M18 & E22 — Expert Working

ICH M15 — AI/ML in Drug Development (Topic Leader)

EDA holds an Expert Working Group seat on ICH M15, developing the global guideline on Artificial Intelligence and Machine Learning in drug development. As Topic Leader, EDA shapes the regulatory framework for AI-enabled submissions, model validation, algorithmic transparency, and data integrity requirements — a role held by very few regulatory authorities globally.

ICH M18 — Framework for Determining the Utility of Comparative Efficacy Studies in Biosimilar Development Programs

EDA participates in ICH M18, new multidisciplinary guideline will outline the factors to consider when determining the utility of comparative efficacy studies (CES) in biosimilar development programs intended to support regulatory approval.

ICH E22 — General considerations for patient preference studies

EDA engages with ICH E22, for patient preference studies (PPS) to inform drug development and related decisions for medical products to optimize the use of patient preference information as input to pharmaceutical product development using a globally harmonised framework

Significance of ICH EWG Leadership

Topic Leadership in ICH EWGs is a prestigious designation held by a select number of regulatory authorities globally. EDA's role reflects formal international recognition of Egyptian regulatory expertise, and directly shapes guidelines governing submissions to all ICH member agencies — including FDA, EMA, PMDA, and Health Canada.

International Achievements

ICMRA AI SC

International Coalition of Medicines Regulatory Authorities

EDA Steering Committee Member

Egyptian Drug Authority

ICMRA AI Steering Committee

About the ICMRA AI Steering Committee

ICMRA's AI Steering Committee coordinates international regulatory policy on artificial intelligence across member agencies including FDA, EMA, Health Canada, TGA, MHRA, and others. The committee develops joint positions, shares regulatory intelligence, and aligns approaches to AI-enabled medicines development and review.

EDA's Membership & Contributions

EDA holds a formal Steering Committee seat, representing the African and EMRO regional perspective in global discussions on AI regulatory frameworks. EDA contributes to joint statements, cross-agency pilot programmes for AI submission review, and the development of shared regulatory assessment principles.

Key Work Streams EDA Contributes To

- Development of ICMRA joint reflection papers on AI/ML in drug manufacturing and clinical development
- Cross-agency alignment on pre-submission frameworks for AI-enabled product applications
- Workforce development initiatives for AI regulatory competency building across member agencies

Strategic Significance

EDA's dual role in both ICMRA AI Steering Committee and ICH M15 EWG creates a uniquely influential position — enabling EDA to simultaneously shape global guidelines (ICH) and coordinate their regulatory implementation (ICMRA). This dual presence ensures Egypt contributes to AI medicines governance at the highest international level.

International Achievements

ICMRA RARE DIS.

International Coalition of Medicines Regulatory Authorities

EDA Steering Committee Member

Egyptian Drug Authority

ICMRA Working Group on Small Population Drug

About the ICMRA Working Group on Small Population Drug Development

Development of a global compendium of terms used in small population drug development for rare diseases.
This compendium will incorporate regulatory references and be made accessible via the ICMRA website.

EDA's Role & Focus Areas

EDA contributes within working group activities on identifing differences in terminology may create confusion and could complicate international collaboration.
By identifying these differences in terminology, and providing clear, standardised regulatory language, we can facilitate global rare diseases drug development

Key Contributions to Committee Work

- Input to ICMRA business case document.
- EDA helped in creation of spreadsheet of 500+ potential terms and definitions reviewed
- EDA participated in the productive discussions held on the compendium's scope, structure, inclusion and exclusion of terms

Patient & System Impact

The compendium's primary purpose is to provide clarity and transparency in a regulatory context, not an exhaustive list or creation of new global definitions. It will highlight where terminology is shared, where it differs by region, and will focus on relevant regulatory concepts rather than broad life sciences terms

International Achievements

AVAREF

African Vaccine Regulatory Forum
(WHO-Supported)

Egyptian Drug Authority

AVAREF — African Vaccine Regulatory Forum
AVAREF Clinical Trial Pilot Program (16-member state reliance network for clinical trials regulatory oversight)

About AVAREF Clinical Trial Pilot Program (16-member state reliance network for clinical trials regulatory oversight)

The pilot project was designed to address commonly anticipated challenges (Irritants) experienced by Product Developers, NRAs, NECs, & AVAREF Secretariat. This includes predictability and consistency in data/Information Requirements for regulatory and/or ethics approval, timelines for regulatory decision making, streamlined processes and/or procedures, and high-quality Scientific Advice and Regulatory Decisions. The pilot therefore focused on regulatory strengthening, harmonization, and excellence, pandemic preparedness, reviewer development programs, creation of access to wide range of expertise within the network and access to Expert Specialist Support.

EDA's Participation & Leadership

EDA participation is important that effective communication channels are established to facilitate communication with DGs, Focal Points and WHO Country Offices. NRAs could also utilize the pooled resources within the network to reduce their backlogs or address. Activation of the CT site network could enhance the realization of the performance targets for increased clinical trials on the continent.

Key Activities & Achievements

1. Pilot a Plausible Model for Clinical Trials Oversight.
2. Develop a Cadre of Experienced Clinical Trial Reviewers
3. Introduce a Centralized CTA Submission System
4. Introduce a centralized electronic platform for review
5. Test the Feasibility and Acceptability of the Proposed Model

Regional Regulatory Leadership

This network has included an additional dimension to ‘reliance’, namely, reliance beyond institutions and transcending to individual expertise within an ecosystem. As such, is clear that this reliance network would be a suitable asset for continental preparedness and hence a foundation for AMA, the continental regulatory agency.

International Achievements

CEPI

Coalition for Epidemic Preparedness Innovations

EDA Regulatory Partner — Epidemic R&D

Egyptian Drug Authority

CEPI — Coalition for Epidemic Preparedness Innovations

About CEPI

CEPI is an innovative global partnership between public, private, philanthropic, and civil society organisations, established to accelerate development of vaccines and biological countermeasures against epidemic and pandemic threats. CEPI funds R&D for priority pathogens including Lassa, Nipah, MERS-CoV, Marburg, and unknown 'Disease X' threats, operating a 100 Days Mission for rapid vaccine development.

EDA's Engagement with CEPI

EDA engages with CEPI as a national regulatory authority supporting rapid review pathways for CEPI-funded vaccine and therapeutic candidates being developed or tested in Egypt and the broader MENA and African region. EDA contributes to the multi-country regulatory intelligence network that helps CEPI navigate complex regulatory landscapes.

Key Areas of Collaboration

- EDA participation in CEPI regulatory stakeholder meetings on epidemic preparedness R&D
- Supporting rapid regulatory review frameworks for CEPI-funded clinical trials conducted in Egypt
- Contribution to international discussions on emergency use authorisation and adaptive licensing
- Sharing EDA's COVID-19 vaccine and therapeutic emergency regulatory review experience as a model
- Engagement with CEPI's 100 Days Mission framework for future epidemic vaccine regulatory readiness

Public Health & Global Security Significance

EDA's CEPI engagement directly strengthens Egypt's epidemic preparedness regulatory infrastructure, ensures Egyptian patients can rapidly access CEPI-funded medical countermeasures in future health emergencies, and positions Egypt as a credible, reliable partner in the global health security research ecosystem — contributing to the collective protection of both African and global populations.

THANK YOU