Global Coalition for
Regulatory Science Research

GCRSR Large Language Models (LLMs) Task Force — Charter

Effective Date: 10-15-2025
Review Cycle: Biannual
Sponsoring Organization: Global Coalition for Regulatory Science Research (GCRSR)
Operating Lead & Secretariat: European Food Safety Authority (EFSA), on behalf of GCRSR

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1. Purpose

Established by the Global Coalition for Regulatory Science Research (GCRSR), a coalition of international government agencies focused on drug and food safety, this Task Force coordinates international regulatory-science approaches to support the uptake of Large Language Models (LLMs) in regulated domains among GCRSR member agencies and beyond. This Charter operationalizes the GCRSR Terms of Reference by enabling coordinated methods, shared evidence, and harmonized (non-binding) practices across GCRSR member agencies.

2. Authority and Non-Binding Nature

The Task Force operates under the GCRSR Terms of Reference and reports to the GCRSR Executive Committee. Its outputs (principles, technical recommendations, coordination mechanisms) are non-binding; domestic regulatory decisions remain the sovereign authority of each member agency.

3. Objectives

1. **Develop harmonized regulatory-science approaches** for evaluating LLM applications in pharmaceuticals and food safety, with potential extension to other regulated products as scoped by GCRSR.
2. **Develop prototypes of LLM regulatory-science applications** and serve as vehicles for translation into regulatory practice ("prototype to policy").
3. **Build a network of technical experts** among participating agencies to facilitate LLM application in the regulatory environment and to share information on LLM regulatory challenges, solutions, and prototypes.
4. **Establish common understanding and practice** tailored to the TREAT principle [Trustworthiness, Reliability, Explainability, Applicability, and Transparency (Tong et al., 2024)] for potential implementation in regulatory contexts across GCRSR member agencies.

5. **Identify regulatory gaps** and propose strategies for LLM use, consistent with the GCRSR guiding principles.
6. **Promote stakeholder engagement** via joint guidance development, public consultation, and international workshops aligned with GCRSR practices.

4. Scope

In scope: Lifecycle oversight and evidence generation for LLMs that affect regulatory decision-making or regulated products, including data governance, model evaluation, deployment, post-market performance, change management, and decommissioning.
Out of scope: Creating binding international rules; endorsing specific commercial products; activities unrelated to regulated products or regulatory processes.
Alignment: Activities align with GCRSR principles of scientific integrity, transparency, collaboration, capacity building, and public-health impact.

5. Membership and Structure

Core Members: the participants from the previous Task Force workshops organized by Swissmedic will be invited to form the core group. Moving forward, membership is **not limited** to government agencies initially represented by the core members; other government regulatory authorities may join as Core Members, subject to Chair invitation and concurrence of Core Members, consistent with this Charter.
Observers: Other relevant international organizations or stakeholders as invited by the Chair in consultation with the GCRSR Executive Committee.

5.1 Governance Roles

- **Chair and Co-Chair:** Representatives from EFSA and FDA serve as Chair and Co-Chair and Operating Lead to establish processes, workplans, and deliverables in the initial term.
- **Secretariat:** EFSA, on behalf of GCRSR, provides administrative support, document control, record-keeping, coordination across working groups, and stakeholder logistics.
- **Steering Liaison:** An FDA representative serves as a liaison from the GCRSR Executive Committee and ensures alignment with GCRSR priorities.
- **Working Group (WG) Leads:** Appointed for time-bound workstreams; accountable for milestones and outputs.

5.2 Decision-Making and Voting

Decision-making and voting operate in accordance with the GCRSR Terms of Reference (ToR).

5.3 Participation Categories & Onboarding

- **Core Members:** Government regulatory authorities with mandates relevant to regulated products or regulatory processes.
- **Observers:** Intergovernmental bodies and stakeholders with relevant remits.
- **WG Participants:** Technical contributors—including non-government experts—may be appointed to support prototyping and translation.

6. Meetings and Work Modality

- **Plenaries:** At least two per year (virtual or in-person) to develop prototypes, review progress, and plan next steps; when possible, one plenary should align with GCRSR meeting cycles to report outputs and future directions.
- **Records:** The Secretariat maintains minutes, decision logs, action registers, and a versioned document repository, consistent with GCRSR practices.

7. Workstreams (Initial)

1. **Prototyping & Pilots:** Inventory prior Task Force activities and outputs, and scope the next prototype development.
2. **Capacity Building & Stakeholder Engagement:** Conduct workshops at EFSA to convene core participants.

8. Resources and Support

- Each agency contributes personnel and expertise consistent with its capacity.
- **Secretariat:** EFSA, on behalf of GCRSR, provides coordination, collaboration tooling, and meeting logistics.
- External funding for joint research, pilots, and consultations may be pursued via international development organizations or grants, with transparent governance consistent with GCRSR policies.

9. Document Control and Revision

- The Secretariat (EFSA on behalf of GCRSR) maintains the authoritative Charter and version history.
- **Amendments:** Proposed by any Core Member; adopted by consensus at a Plenary; reported to the GCRSR Executive Committee.
- **Review:** Biannual review may expand membership and/or scope to reflect technological developments and GCRSR priorities.

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*Tong, W., et al., 2024. Context is everything in regulatory application of large language models (LLMs). Drug Discov Today. 29**,** 103916.