

Call for Proposals

New advanced brokerage for rapid discovery and production of RNA biologics.

Brokerage platform will service the first-ever, equitable global marketplace to enable product developers and researchers access to state-of-the-art design and simulation tools and cost-effective, continuous-flow, scale-independent RNA product production.

Over the past three years, the <u>R3 program</u> developed novel design, simulation, and manufacturing technologies aimed at transforming the economics and accessibility of RNAencoded biologics development. These innovations serve to address the critical limitations of conventional manufacturing by establishing Continuous Flow RNA production and other innovations as a standardized, versatile, and more easily deployable multi-product platform technology that serves dual-use functions:

- In non-emergency periods, R3G enables developers and researchers to access Research Use Only (RUO) and cGMP-formulated RNA for the design, testing, and production of RNA-encoded biologics to treat a wide range of diseases from cancer to rabies.
- 2. In emergency settings, R3G provides geo-distributed surge capacity to rapidly produce RNA-encoded medicines (including vaccines and prophylactics) at the scale and speed required for a globally coordinated, regionally distributed, and equitable pandemic response.

The RNA technology capabilities are substantial: it can support the synthesis of thousands of unique RNA constructs annually and meet the needs of tens of thousands of RNA-encoded medicine designers. Al-driven design and simulation tools developed within the R3G program enhance the technology by enabling real-time optimization, higher yield prediction accuracy, and reduced failure rates. These tools have already been applied to the production of multiple RNA products, including vaccines and therapeutics, that are currently progressing through early regulatory pathways in the US and UK.

The program is now entering its next phase, R3G (RNA Readiness and Response Global), which aims to deploy technologies developed in the R3 phase through a global network of biofoundries. These biofoundries will be capable of cost-effective, cGMP-compliant RNA production at scales ranging from 1 mg (RUO) and 10 mg (preclinical) to 1,000 g (commercial or emergency response)

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To support this rollout, R3G invites proposals to develop and operate an e-commerce brokerage service, underpinned by a digital platform, that connects RNA designers across academia, biotech, and biopharma with a trusted network of GMP certified global biofoundries. This R3G Brokerage Platform will enable users to: Specify RNA product order requirements; access biosecurity and RNA design tools; obtain pricing and delivery timelines; and to submit and manage orders to the R3G biofoundry network.

R3G is anticipated to receive funding from the Coalition for Epidemic Preparedness Innovations (CEPI).

Call for proposals.

We are soliciting proposals for the first of two phases of the brokerage rollout and welcome any additional information as it relates to the future phase 2 as per below:

- Phase 1 (2025 1H 2026): In this minimum viable product (MVP) phase, the brokerage will receive initial orders (targeting around 200-300 runs in the first 12 months) from curated commercial and academic customers to alpha / beta test end-to-end product and service delivery from one or more biofoundries.
- For Future Consideration only: Phase 2 (2H 2026 2028): In its operational steady state, the brokerage service will manage the receipt and allocation of both RUO and cGMP orders to the biofoundries under full commercial conditions. Delivery of this functionality will require additional service layers beyond the core brokerage platform, as outlined below.

The successful applicant for Phase 1 may or may not be selected for Phase 2. It is expected there will be a second CFP for Phase 2.

Phase 1 detailed requirements:

• **RNA designer user interface:** The brokerage platform must allow RNA designers to submit a DNA sequence and specify key RNA features, such as nucleoside modifications, capping, formulation method, and intended dose/dosing schedule. The system will return compatible RNA manufacturer options, delivery timelines, and pricing. Applicants must demonstrate the capability to deliver a high-quality, intuitive user interface that supports complex workflows with minimal training, offering seamless user experience, immersive visual design, and effortless navigation. Proposers should clearly describe their approach to designing, testing, tracking, and iteratively optimizing platform features, including relevant past experience and outcomes.

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- **RNA design tools:** The vendor system will offer various third-party DNA template design tools via a modular, microservices architecture, accessible through a secure API layer. These tools will include, but are not limited to, codon optimization and manufacturability profiling to support translational efficiency and manufacturability of RNA constructs. Applicants are required to demonstrate the capability to deliver a scalable, cloud-native service that integrates seamlessly with the order brokerage system. These services must support efficient data exchange, fault tolerance, and low-latency performance, enabling real-time access to AI-driven design and simulation engines within the RNA order submission workflow.
- Quality assurance and safety controls. The brokerage platform must support the application of quality assurance and safety controls through seamless integration with third-party providers offering information security, biosecurity, payment and billing services, encryption, and Know Your Customer (KYC) services. Applicants must demonstrate the ability to incorporate these services via secure, standards-based APIs. This includes identity verification, biosafety validation, and encryption protocols to ensure the confidentiality, integrity, and non-repudiation of customer data throughout the RNA order lifecycle.
- Order allocation and equity policy enforcement requirements: The brokerage platform must provide capabilities to implement and execute order allocation algorithms that adhere to equity of access policies as defined by the R3G Executive Council. These algorithms must be configurable and policy-driven, enabling transparent allocation of RNA orders across the biofoundry network. Applicants must demonstrate the ability to support allocation logic that supports long-term biofoundry network sustainability. The system must make it simple to accommodate policy changes over time and provide auditability and traceability of allocation decisions.
- Quality assurance monitoring: The brokerage service must also support ongoing quality-by-design oversight by integrating capabilities to inspect and monitor biofoundries for compliance with required certifications, fulfilment of service-level agreements (SLAs), and adherence to most-favoured-nation pricing agreements. Applicants must demonstrate mechanisms for automated verification, exception reporting, and auditability. Sub-contractors may be used to support global inspection and monitoring.
- **Operational reporting and analytics:** The brokerage platform must provide a secure real-time operational dashboard displaying performance metrics across all orders and

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biofoundries. This dashboard must enable comparative analytics, identification of best practices, and support orchestration of load balancing across the network.

Indicative Phase 2 Requirements (For Future Planning Only):

Phase 2 will build upon Phase 1 functionality and transition additional key brokerage functions which were led by the R3G Program Team during Phase 1. These new requirements, which will be finalized following Phase 1, are not within scope for assessment under this Call for Proposal (CFP) but are provided to inform vendors of the anticipated future direction of the brokerage platform and service. A second CFP for Phase 2 is anticipated.

Anticipated Phase 2 functional requirements include:

- Strategic Contracting Relationships: Upstream and downstream contracting for RNA manufacturing inputs (e.g., enzymes, reagents, formulations) and downstream services (e.g., fill-and-finish, cold chain distribution).
- **Technology Landscaping:** Continuous horizon scanning and partnership development within the RNA innovation technology manufacturing ecosystem to ensure integration of leading capabilities and awareness of leading continuous flow technologies.
- Government & Regulatory Engagement: Working with Leap and CEPI to stablish strategic partnerships with governments and health systems (both High Income Countries and Low/Middle Income Countries) to support biofoundry deployment for pandemic preparedness and response, and RNA-encoded biologics innovation.
- Demand Generation: Activation of academic and biopharma partners, including alignment with Wellcome Leap's <u>MARFA and CORFA networks</u> and CEPI's partner networks to stimulate marketplace demand for R3G RNA encoded medicines. Demand generation should be supported and organised with Customer Relationship Management (CRM) Solution.
- Pandemic Preparedness Stress Testing: Coordination and orchestration of periodic biofoundry-led "Live Fire Drill" to demonstrate surge manufacturing capability (10–50 million doses) and comparability, supporting <u>CEPI's 100 Days Mission</u>.

Other considerations

• Business Model Alignment:

The brokerage service must propose a sustainable operating model, which may take the form of either a not-for-profit entity or a commercial enterprise with the R3G





operation being considered part of its Corporate social Responsibility or similar goals. In this case, the business model should align with the R3G program principles and CEPI's Equitable Access Policy. Commercial interests should support public health objectives and equitable access to RNA technologies and products.

• Eligibility and Collaboration:

Proposals are welcomed from individual organisations or multiple organisations and/or individuals with complementary capabilities with a clear operational and leadership execution strategy. Entities with existing experience in this area are encouraged to apply. Applicants with expertise in specific components or categories of this CFP, who are open to being matched with others to deliver a comprehensive solution, are also encouraged to apply and acknowledge their willingness to be matched with others via sharing of contact information.

• Conflict of Interest (COI) Declaration

Applicants must have no actual or perceived COIs with stakeholders within the R3G ecosystem (which include RNA lab equipment manufacturers). Proposals from organisations involved in laboratory equipment manufacturing, RNA therapeutics, vaccine development, or other fields that could present a commercial or strategic conflict with R3G's objectives will not be considered eligible unless the conflict can be managed/mitigated to the reasonable satisfaction of the R3G Executive Council. All applicants must disclose relationships, financial interests, or affiliations that may reasonably be perceived as compromising impartiality or independence.

Application Process

Applicants must submit their completed proposals no later than 30 April 2025 for Phase I (2025 – 1H 2026), in accordance with the submission guidelines outlined below. Deadline will be midnight Pacific Time.

1. Proposal Format and Length

- Proposals must be submitted in English as PDF files, with a maximum length of 8 pages (excluding appendices).
- The core proposal should clearly outline the applicant's technical approach, operational model, team capabilities, related past experience and alignment with the R3G program objectives.

2. Appendices

• Supporting materials such as workflow diagrams, technical schematics, User Interface (UI) mock-ups, or performance data may be included in an appendix. These materials



should be referenced appropriately within the main document but will not count toward the 8-page limit.

3. Costing and Funding Requirements

- Proposals must include a detailed timeline, budget outlining estimated cost and resource allocations.
- Applicants should also indicate their preferred commercial model, and any assumptions made in cost estimation.

4. Submission and Contact

- Applications must be submitted via the <u>Google Form</u> by midnight on 22 April 2025.
- Receipt of submission will be acknowledged within one week. Late or incomplete applications may not be considered.

5. Evaluation Process

- Selection will be at the full discretion of the Leap, but in general proposals will be evaluated against the criteria defined in this CFP, including:
- Technical and operational capabilities including similar related e-commerce or brokerage experience
- User Interface/User Experience (UI/UX) design quality and development approach
- Platform scalability and interoperability
- Delivery feasibility and team expertise
- Commitment to R3G principles, including equity of access
- Cost-effectiveness and value for money
- Shortlisted applicants may be invited to follow-up interviews or requested to submit additional clarifications.



