# Request for Proposals:
# Synthetic Route Design Initiative
## Accelerating Access: Route Design for Pre-Clinical Molecules Discovered in the Commonwealth of Virginia

Offered by: The Medicines for All Institute at Virginia Commonwealth University

Funded by: The Joan and Morgan Massey Foundation

Date of Issuance: April 28, 2026
Signed Confidentiality Agreement Due Date: May 19, 2026
Application Due Date: June 2, 2026 by 5pmET
Estimated Award Date: June 30, 2026
Projected Project Start Date: July 13, 2026

**Required Documents**

1. Application
2. Signed Confidentiality Agreement (note early due date)

**Single Point of Contact**
Shannon Weatherly
Program Management Lead, Commercial Services
Medicines for All Institute, Virginia Commonwealth University
Email: weatherlysd@vcu.edu

# THE MEDICINES FOR ALL INSTITUTE'S HISTORY & WORK

Created in 2017, The Medicines for All Institute (M4ALL) provides pharmaceutical development and manufacturing services in support of a mission to improve access, affordability, sustainability, and commercialization of high priority medicines. Founding support was received from The Gates Foundation (GF) and Virginia Commonwealth University (VCU). M4ALL has grown, and is still growing, toward being a solution not only for global health issues, but also for those here at home in Virginia and the US.

As a mission-driven organization, M4ALL aims to provide services to customers who can provide social impact, financial sustainability, and ideally both. We aim to regularly review and pursue business and customers that can ensure our portfolio delivers impact and long-term financial sustainability. Our portfolio development efforts are driven by active engagement with communities and customers who require our services (e.g., global health, domestic R&D, small and emerging biotechnology companies).

## M4ALL's Suite of Services

M4ALL has five service offerings with a sixth coming on board in early 2027 with the construction of a kilogram facility.

A. **Route Design**: Using baseline chemistry and all available factors, the design of synthetic routes for clinical and commercial scale manufacturing of active pharmaceutical ingredients (API)

B. **Technoeconomic Analysis**: Using baseline chemistry and all available factors, determine key cost drivers of API; Identification of less expensive, safer, and/or more readily available and easier to access key starting materials involved in the making of API

C. **Analytical Services**: A wide range of services including, but not limited to:
   a. Spectroscopy Services
   b. Chromatography Services
   c. Reference Standard Supply (catalog sales and contract basis)
   d. Polymorph screening assessment
   e. Polymorph physicochemical properties assessment vs. desired target product profile performance

D. **Process Research & Development**: A wide range of services for the purposes of ensuring scalability of API from Route Design
   a. Determine feasibility and baseline performance of design strategies for target drug identified in Route Design
   b. Establish practical unit operations for each process step, reference standards for product and impurities, and in-process assays
   c. Establish optimal scalable uniter operations in each process step (i.e., reaction, workup, purification, isolation, analytical methods, in-process controls)
   d. Demonstrate efficient processes with Batch Reports at 100+gram scale

**E. Technology Transfer:** Support tech transfer to partner or partner-nominated third-party manufacturer

F. **Sale of drug substance (API and intermediates)**: Preparation and safe manufacturing of API for use by internal and external customers
   a. Preparation of multi-kilogram quantities of API for low-volume commercial applications and/or demonstration
   b. Advanced pharmaceutical manufacturing capabilities in continuous process development (e.g., flow chemistry)
   c. Development of safer processes with lower environmental impact (i.e., green chemistry practices)

## PROJECT DESCRIPTION

The Synthetic Route Design Initiative, led by The Medicines for All Institute (M4ALL) and funded by The Joan and Morgan Massey Foundation, seeks applicants for the purposes of advancing pharmaceutical manufacturing in the Commonwealth of Virginia. Requests for Proposals (RFP) relevant to this effort will seek assistance from M4ALL for the purposes of conducting a Route Design project at no cost, which will include synthetic route scouting exercises, technoeconomic analysis, and the provision of final documentation for review by the applicant, which will include an Executive Summary and accompanying PowerPoint with all information related to the newly proposed synthetic routes. Any services beyond the Route Design are not included in this project.

M4ALL exists to transform how medicines are made and ensure their availability to all who need them. Within the current offering of services, M4ALL conducts Route Design projects to determine, based upon baseline chemistry, new synthetic routes which are tested against the technoeconomic analysis seeking to identify major cost drivers. Once these cost drivers are identified, M4ALL will engage in literature review and additional work to develop new routes which will be evaluated for commercial scalability. Applicants should include what conditions they are seeking to prioritize in the project proposal, as these will also determine the feasibility of the project and M4ALL's ability to have a positive impact on the work proposed. Factors to be considered include:

- Assess target APIs for opportunities to improve manufacturability and reduce costs
- Innovate efficient, pragmatic synthetic route options to target APIs that align to ideals of manufacturing:
    - High Quality & Reproducibility
    - High Productivity Space-Time-Yield
    - Minimal # of Synthetic Steps
    - High Atom Economy. Low PMI.
    - Secure Supply Chain
    - EHS-favorable
    - IP favorable
- Prioritize candidate routes vs. client objectives (commercial and technical) that reflect partner objectives
- Progress partner-selected routes into Process Research & Development for validation

M4ALL exists to transform how medicines are made—developing scalable, cost-effective, and environmentally responsible processes enabling broader access to essential therapies. This initiative reflects our commitment to regional innovation, global health equity, and collaborative problem-solving. Submitted proposals should include an explanation of how the project meets these above listed priorities. Other resources for learning about M4ALL are available here: The Impact of Medicines for All Institute

# PROJECT PURPOSE

The purpose of this project is to assist Virginia-based entities in developing new, improved synthetic routes for a novel, small molecule in the pre-clinical phase of development.

# ELIGIBILITY

## 1. ELIGIBLE APPLICANTS

Applicants must be within the Commonwealth of Virginia. Applications from outside of Virginia will not be considered for this project.

- Academic researchers
- Pharmaceutical start-ups
- Biotechnology companies
- Entities engaged in drug discovery & research

## 2. ELIGIBILITY REQUIREMENTS

Only projects supporting novel, small molecules in the pre-clinical development stage will be accepted. Applicants may only exist within the Commonwealth of Virginia.

## 3. COMPLETING THE APPLICATION

### A. CONFIDENTIALITY AGREEMENT

A sample Confidentiality Agreement (CDA) has been provided by M4ALL in this application package. If this CDA is not sufficient for the applicant organization, the applicant may submit their own CDA for review. The CDA, regardless of which is used, is due to Shannon Weatherly (weatherlysd@vcu.edu) no later than May 19, 2026 by 3pmET.

The CDA will be reviewed by VCU/M4ALL and if there are questions, will revert back to the applicant at the contact email address provided in the application. Failure to have a signed, completed CDA in place by the application due date, June 2, 2026, makes an application ineligible. The time in between submission of the CDA and the application due date will be used to determine if M4ALL and the applicant agree on conditions of the agreement.

### B. WRITING THE PROPOSAL

All proposals must be submitted via email to Shannon Weatherly (weatherlysd@vcu.edu) no later than 5pmET on June 2, 2026. Proposals will not be accepted in any other way.

All proposals must follow the guidelines listed below and answer the questions provided on page 6.

- No more than 10 pages in length
- Times New Roman Font in pitch no greater than 11 and no less than 9 (9 may be used in charts or graphs)
- Single spaced
- The document must be submitted in PDF format. M4ALL may request other formats in the event the PDF, once delivered, cannot be downloaded or viewed properly.
- The cover page, which is not included in the page count, must include the following information:

## Demographic Information

1. **Name of Applicant Organization**
2. **Contact Person**
3. **Contact Person Email**
4. **Contact Person Phone Number**
5. **Name/Code for Proposed Molecule**

The scoring rubric, including weights for various sections, are included on pages 7 and 8 of this document. Please review these and understand the requirements for each section for scoring purposes.

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### Questions for Completion

Please answer all of the following questions completely and fully. Scoring of these questions will be based upon the scoring rubric provided on page 7.

1. Fully describe the molecule presented in this proposal. At a minimum, provide the structure of the molecule and a full description of the stereochemistry.

2. Provide as much information as possible pertaining to the existing/conceptual synthetic route (baseline chemistry), which may include the complete synthetic route and/or procedural details, as well as any specific regulatory conditions pertaining to the manufacturing of this molecule, if known.

3. Prioritize the following goals and explain the rationale for the order given.
   A) Cost Reduction
   B) Safer Chemistry
   C) Greener Chemistry
   D) Develop Commercially Viable Route
   E) Other (Add your own priority)

4. What is the anticipated potential clinical impact of this molecule?

5. What is the potential for further collaborative work on this molecule with M4ALL (*Refer to M4ALL's Suite of Services in this application*)?

6. Why should this molecule be chosen for this project? Will this project positively impact regional innovation, global health, and/or collaborative problem-solving?

7. Based on your knowledge of this drug's biological activity, are you aware of any other drugs on the market with similar treatment potential?

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### Evaluation Rubric

#### 1. Molecular Description (10%)

Criteria: Structure, stereochemistry, and clarity of molecular presentation

| | |
|---|---|
| 5 | Complete & accurate molecular structure with detailed stereochemistry, includes diagrams or models |
| 3 | Basic structure provided; stereochemistry partially described or unclear |
| 0 | No molecular description provided |

#### 2. Synthetic Route/Baseline Chemistry (10%)

Criteria: Completeness, feasibility, and innovation of synthetic pathway

| | |
|---|---|
| 5 | Fully detailed synthetic route with procedural steps, reagents, yields, and rationale |
| 3 | Conceptual route outlined, lacks procedural depth or clarity |
| 0 | No baseline chemistry provided |

#### 3. Prioritization of Project Goals (10%)

Criteria: Logical prioritization and justification of goals

| | |
|---|---|
| 5 | Clear, well-reasoned prioritization with strong rationale for each goal; includes thoughtful additional priorities |
| 4 | Prioritization mostly logical; rational provided, but lacks depth |
| 3 | Goals listed with limited explanation; prioritization unclear |
| 2 | Goals mentioned but poorly prioritized or justified |
| 0 | No prioritization and rationale provided |

#### 4. Clinical Impact Potential (20%)

Criteria: Relevance, novelty, and therapeutic value

| | |
|---|---|
| 5 | Strong evidence of significant clinical impact; addresses unmet medical needs or improves current therapies |
| 4 | Moderate impact potential; some novelty or therapeutic relevance |
| 3 | Limited impact; overlaps with existing treatments |

| | |
|---|---|
| 2 | Minimal clinical relevance or unclear therapeutic value |
| 0 | No clinical impact provided |

5. **Collaborative Potential with M4ALL (20%)**

Criteria: Alignment with M4ALL services and potential for synergy

| | |
|---|---|
| 5 | Clear opportunities for collaboration; proposal aligns well with M4ALL's capabilities & services OR clear alignment with the mission of M4ALL |
| 4 | Good to moderate potential for collaboration |
| 0 | Minimal to no collaboration potential |

6. **Strategic Justification for Selection (20%)**

Criteria: Broader impact on innovation, health, and collaboration

| | |
|---|---|
| 5 | Strong evidence of significant impact on regional innovation, global health and/or collaborative problem-solving |
| 4 | Good impact potential; addresses at least two impact areas |
| 3 | Moderate impact potential; impact area(s) mentioned, but not well developed |
| 2 | Weak justification; vague or generic claims |
| 0 | No impact explanation provided |

7. **Comparative Drug Landscape (10%)**

Criteria: Awareness of similar drugs and differentiation

| | |
|---|---|
| 5 | Thorough comparison with existing drugs; highlights differentiation & market positioning |
| 4 | Good awareness of similar drugs; some differentiation discussed |
| 3 | Mentions similar drugs; limited analysis provided |
| 2 | Minimal awareness of similar drugs; lacks comparison or differentiation |
| 0 | No comparative analysis provided |