

REQUEST FOR INFORMATION

**High throughput lipid nanoparticle synthesis system**

May 3, 2022

Enabling Technologies Consortium™

Request for Information

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# Introduction

## About Enabling Technologies Consortium™ (ETC)

The Enabling Technologies Consortium™ (ETC) is comprised of pharmaceutical and biotechnology companies collaborating on issues related to pharmaceutical chemistry, manufacturing, and control with the goal of identifying, evaluating, developing, and improving scientific tools and techniques that support the efficient development and manufacturing of pharmaceuticals. The purpose of this consortium is to identify pro-actively high-value opportunities to deliver innovative technologies where the business case is compelling and collaboration with the broader external community is required.

## Request for Information

Publication of this Request for Information (RFI) is the first step by ETC to solicit interest in collaborating on the project titled “**High throughput lipid nanoparticle synthesis system”** The information collected during this process along with subsequent interviews will be used for evaluation purposes. Depending on the responses received ETC may choose to select a collaborator solely based upon its response to the RFI or may choose to refine project requirements and subsequently release a Request for Information (RFI) to aid in the collaborator selection process.

## Disclaimer

The contents and information provided in this RFI are meant to provide general information to parties interested in developing the project “**High throughput lipid nanoparticle synthesis system”.** The successful respondent selected by ETC will be required to execute an Agreement that will govern the terms of the project. When responding to this RFI, please note the following:

* This RFI is not an offer or a contract
* Responses submitted in response to this RFI become the property of ETC
* Respondents will not be compensated or reimbursed for any costs incurred as part of the RFI process
* If ETC receives and responds to questions from RFI respondents, ETC reserves the right to anonymize the questions and make the questions and ETC’s responses available to all respondents via our website
* Responses to RFIs should contain only high-level discussions of product development efforts and should not contain trade secrets or confidential information. ETC does not make any confidentiality commitments with respect to RFI responses but agrees not to publicly distribute RFI responses outside of ETC or share RFI responses with other respondents.
* ETC is not obligated to contract for any of the products or services described in this RFI
* ETC reserves the right to:
	+ Accept or reject any or all proposals
	+ Waive any anomalies in proposals
	+ Negotiate with any or all bidders
	+ Modify or cancel this RFI at any time

## RFI Contact Information

All questions and inquiries regarding this RFI should be directed to:

Ms. Fatou Sarr

ETC Secretariat

c/o Faegre Drinker Biddle & Reath, LLP

1500 K St NW

Washington DC, 20005-1209

202.230.5148

info@etconsortium.org

<http://www.etconsortium.org/>

## Anticipated Time Frames for Evaluation and Selection Process\*

Issue RFI May 3, 2022

Questions on RFI due May 17, 2022

ETC responds to any RFI questions May 31, 2022

Responses from potential collaborators due June 14, 2022

Invitations sent to respondents for presentation June 30, 2022

Presentation to ETC by respondents Jul 5 – Jul 22, 2022

Select finalists for RFI or select a collaborator Jul 25 – Aug 5, 2022

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after June 14, 2022*** ***will not benefit from full consideration and may be excluded from the selection process.***

## Project Scoping and Project Execution

ETC project sponsors will work with the selected collaborator to define the project scope and work to finalize a Statement of Work (SOW) for the project which describes project timelines, milestones, budget, deliverables, etc. Depending on the project, the scoping exercise will be conducted via email, web-meetings, and/or an in-person workshop. Following finalization of the SOW, the project will be brought forward to the ETC Board of Directors to authorize moving to execution.

Once authorized by the ETC Board of Directors, the ETC Secretariat will work with the selected collaborator to negotiate and finalize a contract between the two parties, leveraging ETC’s Development Agreement and Non-Disclosure Agreement accelerator templates. In parallel to this negotiation, the Secretariat will also work to finalize and execute our internal project Charter between participating ETC members.

## Intellectual Property

ETC acknowledges that this project, or aspects thereof, may require the use and incorporation of existing intellectual property and/or the development of new intellectual property in order to successfully complete the project.

### Existing Intellectual Property

* ETC as an organization will not engage in negotiations with the owner of any intellectual property on the respondent’s or ETC’s behalf;
* It is the responsibility of the respondent to conduct an intellectual property search and take all necessary steps to ensure their proposed project will not infringe or misappropriate any intellectual property right of a third party and/or obtain all necessary consents, assignments and licenses to provide the solution in the project proposal.

### New Intellectual Property

With most projects conducted with ETC:

* All commercialization rights will reside with the collaborator;
* ETC will not assume ownership of any intellectual property (IP) developed by the collaborator or expect royalties from future commercial sales.

# Project Information

## Possible Project Sponsors

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| AbbVie, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Genentech, GlaxoSmithKline, Johnson and Johnson. |

## Description

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| Development of lipid nanoparticle (LNP)-based delivery system usually requires tremendous amount of screening effort on the chemistry of lipids, lipid/cargo ratio, and overall composition of all lipid components such as ionizable lipids, helper lipids etc. All these formulation parameters have critical impact on the physicochemical properties of lipid nanoparticle and overall therapeutic outcome of delivery system. Currently there are various publications for synthesis of some of the lipid components in high-throughput combinatorial manner [1]. However, very limited data exists on incorporating the various lipid components and preparing LNP in high-throughput manner. Design of experiment (DoE) strategy provides an additional tool in selecting the optimal combination of formulation parameter, but also require lot of efforts in formulation preparation [2]. While both approaches emerge as front-edged techniques in the LNP development, there is clearly a need for establishing the capability in high-throughput preparation of LNP systems. Thus, incorporating different combinations of LNP components in high-throughput manner is unmet need.Microfluidic technology has been extensively applied in LNP development, enabling a reproducible, user-friendly preparation of LNP systems [3]. Though an off-shelf microfluidic device with 24 channels for parallel formulation was reported in preparing LNP [4], current commercially available process for LNP using microfluidic technique only allows formulating single combination of parameters at one time. It is very challenging and time-consuming to scale up the number of LNP to cover all potential combinations of formulation parameters and to achieve the formulation with the optimal physiochemical properties, therapeutic efficiency, and stability. In addition, preparing small volume of lipid stock manually is prone to human error and time-consuming. Thereby, a platform that enables formulating LNP in a high through-put manner represents a significant contribution to the development of LNP-based delivery system for various therapeutic modalities. Given to the unmet need to address the problem mentioned, we propose to develop a high-throughput preparation platform that enables simultaneous formulation of LNP (>10) with different processing parameters using microfluidic technique. The device may include a fully automated liquid handling robotic system capable of preparing low volume of lipid stock with great precision, multiple channels for organic/aqueous phases, paralleled microfluidic chips, together with a pressure driven system capable of minimizing dead volume in the system and therefore materials need. Considering this platform will be applied in formulation screening at early research stage where material availability is limited, small-scale preparation is desirable. Representative LNP screening from the proposed equipment and method will be selected for further scale-up. The major benefits from this proposal are allowing labor/time saving preparation of LNP, minimizing manual error between different batches, and facilitating the screening capability in LNP development. [1] A. Akinc, et al., Nat Biotechnol, 2008, doi: 10.1038/nbt1402[2] A. Hashiba, et al., J Controlled Release, 2020, doi: 10.1016/j.jconrel.2020.08.031[3] A.K.K. Leung, et al., J Phys Chem B, 2015, doi: 10.1021/acs.jpcb.5b02891[4] D Chen, et al., J. A. C. S., 2012, doi: 10.1021/ja301621z  |

## Requirements

### Necessary Hardware and Software Requirements

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| **Hardware Requirements:** * **Robotic Liquid handling system**
* Capability of handling broad range of liquid types and volumes and non-contact dispensing.
* **Parallel microfluidic LNP preparation**

 - Capability of preparing >20 LNPs at a time - Sample size 0.1-1 ml - The equipment can prepare variety of NP delivery systems, i.e., lipid-based, polymeric-based, etc. * **Benchtop, compact, reasonable size**

**Software Requirements:*** **A simple and intuitive interface for use by non-specialists is required:**

**-** Setup to enable a sequence of analyses (e.g., sampling interval, method parameters, number of samples, etc.) should be available in a user-friendly fashion that requires minimal training or minimal special expertise |

### Optional Hardware and Software Requirements

|  |
| --- |
| n/a |

### Availability Requirements

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| * Commercially available and supported system.
* Any requisite service on the instrument should be available globally.
* Vendor-provided, hardware and software support is expected for the reasonable life of the product.
* Hardware, software, and firmware updates should be field deployable and available at reasonable cost following launch of the commercial technology.
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### Licensing Requirements for Commercialized Product

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| * Software will be licensed to ETC participants at no cost during (i) development and (ii) a mutually agreed beta testing period.
* Thereafter, software will be available for licensing on a perpetual basis or subscription basis at the option of customer.
* Software shall be available for self-hosting by (or on behalf of) customer even if the collaborator elects to make a SaaS alternative available.
* The collaborator shall make available industry standard support.
* Ownership of data generated on system resides with customer.
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# Criteria for Evaluation

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| The ETC will evaluate the responses to this RFI based on the respondent’s ability to:* Provide responses reflecting a desire to participate in collaboration.
* Meet the functional, performance, and technical requirements described in this RFI as evidenced by the RFI response and presentations made to ETC.
* Provide a cost-effective solution that is compatible with the goals of the project.
* Demonstrate domain expertise and an ability to work collaboratively with the ETC in development of high throughput lipid nanoparticle synthesis system.
* Provide a superior level of customer service and technical support, both pre-installation and post-installation to clients.
* Discuss potential partnerships and current development efforts that show similarities to this RFI.
* Provide any additional capabilities that may differentiate them from other potential collaborators.

Please note that due to the volume of responses received, ETC only provides general updates related to the status of the review process and will not provide individualized feedback as to why a particular proposal was not selected by ETC. |

# Respondent Profile

*(To be completed by respondent)*

Please provide information to the following:

## Company/Organization Information

|  |  |
| --- | --- |
| Company/Organization Name |  |
| Address |  |
| City |  |
| State |  |
| Country |  |
| Zip Code |  |
| Website |  |

## Primary Contact Person

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| Email address |  |
| Phone Number |  |

## Company/Organization Overview

Provide a brief overview of your company/organization including number of years in business, number of employees, nature of business, description of clients, and related products developed and commercialized to date.

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## Parent Corporation and/or Subsidiaries

Identify any parent corporation and or subsidiaries, if appropriate.

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## Summary of Expertise

Give a brief description of your company/organization’s expertise in the area/field related to this RFI. Include any experience working on projects with Consortia/Associations.

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## Standards Certifications

List any certifications currently held, including date received, duration, and renewal date.

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## Goals and Strategic Vision

Provide a summary of your company/organization’s short term and long-term goals and strategic vision.

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## Miscellaneous

Please enter your response to each requirement using the guidelines provided in the tables below. If additional documentation or schematics are required to respond to a particular question, please answer the question as succinctly and accurately as possible and reference supplemental attachments.

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# Company/Organization Response to RFI (*to be completed by RFI respondent)*

## Proposal

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## Functional Requirements & Specifications

Refer to the following Functional Requirements and Specifications checklist which summarizes the collective requirements and specifications by the member companies participating in the project.

Based upon your proposed approach to deliver a solution, provide a response to each checklist item along with comments and assign one of the following Codes to each item:

|  |  |
| --- | --- |
| A | Current capability of existing product |
| B | Able to add capability as requested |
| C | Able to add capability with modification to ETC request |
| D | Unable to add capability |

| Feature | Requirement | Code | Vendor Comments |
| --- | --- | --- | --- |
| **Overall** | Benchtop, compact, reasonable size |  |  |
| **Robotic Liquid handling system** | Capability of handling broad range of liquid types and volumes and non-contact dispensing |  |  |
| **Parallel microfluidic LNP preparation** | Capability of preparing >20 LNPs at a time |  |  |
| **Parallel microfluidic LNP preparation** | Sample size 0.1-1 ml |  |  |
| **Parallel microfluidic LNP preparation** | The equipment can prepare variety of NP delivery systems, i.e., lipid-based, polymeric-based, etc. |  |  |

## Estimated Timeline

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## Estimated Project Cost

The overarching goal of ETC is to help bring innovative technologies to the commercial marketplace in partnership with third parties.  Aligned with that goal, participating ETC members will provide resources in the form of funding and subject matter expertise to support the development of this project.  While ETC will entertain all proposals received, regarding funding from ETC, please consider the following:

* Proposed budgets should be provided as **fixed-costs in US Dollars;**
* When partnering with a commercial vendor, any monetary resources provided by ETC should be viewed as seed funding to supplement the total development costs with the collaborator investing as well;
* When partnering with an academic or non-profit organization, any monetary contributions requested from ETC should be for the total project costs, inclusive of indirect costs (i.e., proposed costs should be inclusive of any indirect or other hidden costs);
* Include a payment schedule, based upon time from project start and/or milestones.

Please describe below project costs, including not only the total project costs but also costs to be paid by ETC and any costs borne by your organization.

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## Commercialization and Support

The overarching goal of ETC is to help bring innovative technologies to the commercial marketplace in partnership with third parties.  Aligned with that goal ETC looks to collaborate on projects which will result in products that are commercially available and supported in the marketplace.

* With most projects, all commercialization rights will reside with the collaborator;
* ETC will not assume ownership of any intellectual property (IP) developed by the collaborator or expect royalties from future commercial sales.

Please describe your organization’s plans for commercialization and support of this technology following the successful conclusion of this project.  If your organization is not a commercial entity (e.g., academic or non-profit), please describe any plans related to the availability of the technology following the successful conclusion of the project. Note that for projects where there isn’t an expectation of a commercial product or service offering, (e.g., research and development project, services-only project) it is expected that each ETC member participating in this project will be provided a non-exclusive, royalty-free license to the output of the project and any new Project IP developed under this project for commercial purposes.

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