

REQUEST FOR INFORMATION

**High Throughput Solubility Measurement Platform**

August 22, 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 Solubility Measurement Platform.”** 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 Proposals (RFP) 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 Solubility Measurement Platform.”** 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/>

## Important Dates\*

Issue RFI August 22, 2022

Questions on RFI due September 12, 2022

Responses from potential collaborators due October 17, 2022

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after October 17, 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, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Merck, Pfizer, Takeda, Zoetis |

## Description

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| Current high throughput platforms for solubility workflows present challenges for the measurement of accurate, reliable, and reproducible solubility data across a range of experimental conditions and solvent types. The ETC aims to identify new, unique, and integrated solutions to address these challenges and to partner with vendor(s) to evaluate development of a platform that is robust, automated, high-throughput and enables customization of workflows/recipes by expert users but also accommodates routine workflow execution by general users. The workflow may include hardware and software components for necessary unit operations, for example, solid dispensing, liquid dispensing, equilibration and mixing, solid-liquid separation to sample a solution aliquot, sample preparation for analyses, and analyses of the residual solids. Measurement of accurate and reproducible solubility data with current technologies can be particularly challenging for highly viscous or volatile solvents. The proposed technology/platform solution is expected to enable solubility measurement in a wide range of conditions such as, organic solutes, bio-relevant and process-relevant media (organic and aqueous solvents/solvent mixtures), temperature, and pH. It is valuable to develop capabilities that allow for flexibility of solute requirement (e.g., mg charged per vial) to support future use in early-stage research and late-stage development in the pharmaceutical industry. Potential errors in solubility measurement often arise from solid-liquid separation, sample dilution and preparation prior to analyses, and sample integrity during different steps of the workflow. It is required that the proposed technology/platform solution ensure appropriately contained sample/material maintenance and handling during the different constituent unit operations in the proposed workflow. A robust, automated, user-friendly high throughput platform that can execute reliable solubility measurement is desired and the development and application of creative and innovative solutions to address current challenges is encouraged, including with potential integration to combine different existing technologies. |

## Requirements

### Necessary Hardware and Software Requirements

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| * **Hardware Requirements:**
	+ Materials of construction compatible with organic solvents and aqueous mixtures of acidic and basic pH
	+ End-to-end automated system, including, sample preparation (solids + liquids) -> equilibration -> quantitative solubility measurement -> data output
	+ **Experiment preparation requirements:** hardware capabilities to execute,
		- Solids dispensing,
		- Liquids dispensing,
		- Vial and/or plate sealing.
	+ **Equilibration requirements:** hardware capabilities to execute and achieve,
		- Mixing technology appropriate for both organic and aqueous solvent systems. Consider impact of mixing on particle attrition and downstream separation of solids from liquids.
		- Temperature control between 0 °C to 70 °C (preferred -20 °C to 120 °C)
		- Extended (variable) time for equilibration
		- Solvent retention/containment throughout measurement and storage duration.
		- Stable/controlled sample storage prior, during and after measurement.
	+ **Analytical measurement requirements:**
		- Ability to measure solubility from 0.1 mg/mL - 100 mg/mL in process-relevant organic solvents/mixtures (additionally, a wider range of 0.001 mg/mL– 200 mg/mL is desirable for aqueous/bio-relevant media).
		- Ability to measure solution pH for aqueous mixtures
		- Ability to filter and isolate residual solids after equilibration for high-throughput-friendly analysis of solids (ex. XRPD, FTIR, Raman) after solubility measurement
* **Software Requirements**
	+ **Automated platform, excluding analytics:** Ability to create user-defined step-by-step sequence/recipe for preparing samples, unit operations, executing solubility measurement
	+ **Automated platform, data management:** Ability to export parameters and raw data & results out of parent software and accessibility to non-expert users in an open, non-proprietary file format (e.g., JSON, XML, CSV) suitable for import into other software.
	+ **Software for analytics**: Flexibility of software platform(s) to analytical techniques being proposed for solute and solution measurement.
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### Optional Hardware and Software Requirements

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| **Optional Hardware Requirements:*** End-to-end automation is desirable (e.g., solids dispensing, solvent addition, temperature adjustment, and sampling/analysis)
* Universally (organic/aqueous) compatible filtration technology at experimental temperatures to separate and collect solids from liquid

**Optional Software Requirements:*** Overarching parent software able to control/operate individual/existing component platforms
* Cost-effective automated scheduling capabilities to execute sequential experiments, parallel unit operations in the same or sequential experiments, and plan/execute experiments in staggered queues.
* Cost-effective automated scheduling of follow-up experiments based on results of AI enabled experimental design and execution
* Automation of analytics for measurement of solute concentration, pH and solid form determination.
* Platform integrates with existing analytics software via universal file formats for results readout.
* Parameters, data, and results stored in standardized format (e.g., Allotrope, AnIML, etc.)
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### 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 are 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 Solubility Measurement Platform.
* 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 on your proposed approach to deliver a solution to this request, provide a response along with supporting comments to each checklist item. Please assign one of the following Codes (A, B, C, D – guidance tabulated below) to each item. Please provide descriptive, technical and detailed responses to the proposed requirements/requests in the respective section for Vendor Comments:

|  |  |
| --- | --- |
| 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 |

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| --- | --- | --- | --- |
| Feature | Requirement | Code | Vendor Comments |
| Hardware Requirements: General | Equilibration of organic and aqueous/biorelevant solvent media at controlled temperatures |  |  |
| Hardware Requirements: General | Ability to measure pH (only for aqueous). Please describe how pH is measured e.g., pH indicator dye, pH probe etc.  |  |  |
| Hardware Requirements: General | Post-equilibration, mechanism to easily separate and access solids for form analyses (e.g., XRPD, FTIR, Raman) or determine form without solid-liquid separation at all. Please describe capabilities and/or proposed solution. |  |  |
| Hardware Requirements: General | Post-equilibration, ability to measure broad range of solubility (1 ug/mL to 100 mg/mL, with desire to reach 200 mg/mL) via an appropriate analytical technique. Please describe analytical technique and range of concentration. |  |  |
| Hardware Requirements: General  | Required Temp Range 0 – 70 CDesired Temp Range -20 to 120 C.Please describe temperature range for all unit operations (locations) in a single workflow, opportunity to expand temperature range to meet desired range above, and what heat-transfer technique can be applied to enable temperature control.Please describe if multiple temperatures can be maintained for the different locations in a single workflow. |  |  |
| Hardware Requirements: General  | Ability to store samples under controlled conditions (temp, sealed, etc.) during sample preparation, sample analyses, and post analyses, including for non-ambient solubility measurements. Sample preparation, sample analyses, and post analyses may be maintained at different temperatures based on appropriate needs. Please describe temperature control range capabilities available and/or proposed for each of the three. |  |  |
| Hardware Requirements: General | Describe sealing mechanism over equilibrium conditions and ease to reseal and sample out of repetitively. (i.e., Capper/decapper, capmat that still limits evaporation)  |  |  |
| Hardware Requirements: General | Please describe technique used to separate solids from liquids for downstream analytics (if necessary). |  |  |
| Hardware Requirements: General | Describe options for filtration/separation techniques to be carried out at equilibrium conditions for elevated temperature solubility.  |  |  |
| Hardware and Software: General | Please describe options for end-to-end execution of components of proposed solubility workflow. Raw material dosing to sample analysis in a single execution.  |  |  |
| Hardware and Software: General | Multi-tiered user access ability: Please describe options for (1) customization of workflows/recipes by expert, full-access users and also (2) guided, walk-up, routine workflow execution by general users. |  |  |
| Hardware Requirements: General | Ability to apply liquid handling in workflow for solvents with wide viscosity, 0-200 cP. |  |  |
| Hardware Requirements: General | Describe Dynamic Range and Accuracy of solid and liquid handling techniques (as applicable). Please describe for supporting organic and aqueous media, if different, for proposed platform. |  |  |
| Software Requirements: General | Describe options to calibrate parameters for liquid and solid handling techniques. Please describe for supporting organic and aqueous media, if different, for proposed platform. |  |  |
| Hardware Requirements: General | Material compatibility of instrument with variety of solids and liquids. Consumables available and compatible for multiple pHs, temperatures, organic vs aqueous liquids. Please describe options for self-cleaning of instrument components, if any. |  |  |
| Hardware Requirements: General | Describe the agitation mechanism available: stirring, shaking, sonicating, multiple |  |  |
| Hardware and Software Requirements | Describe the cycle time for a solubility measurement, is a kinetic profile possible or just equilibrium (i.e., how frequent can timepoints be)  |  |  |
| Hardware and Software Requirements | Describe the cycle time for single unit operations:1) Powder dose2) Liquid dose3) Filtration4) DilutionPlease indicate if more than 1 sample can be processed simultaneously in any/all of the unit operations above. |  |  |
| Hardware/Software: Safety | What international electrical safety guidelines will or can the system be qualified for global use (NRTL, CE, etc.).Describe electrical requirements for platform (e.g., voltage etc.). |  |  |
| Hardware Requirements: General | Please describe other utility requirements for unit operations in proposed platform e.g., vacuum, pressurized gas, cooling fluids, etc.  |  |  |
| Hardware/Software: Safety | Describe what machine guarding options are currently available and potentially implemented to ensure end-user safety. Describe the ability for ‘smart’ or ‘auto’ restart execution if machine guarding is tripped e.g., interlock, light curtain, pressure pad. |  |  |
| Hardware Requirements: Safety | Describe the containment options available for handling of potent compounds or volatile liquids in solubility measurement (ventilated balance enclosure, purge box, isolator box).  |  |  |
| Software Requirements | Describe if agnostic data output or ability to export data to 3rd party software are possible. If so, please share potential data formats for output and data transfer or integration to other software. Be sure to highlight any data formats (e.g., JSON, XML) and/or standards (e.g., Allotrope, AnIML).  |  |  |
| Software Requirements (optional) | Describe options of software scheduling capabilities for multiple executions in queue. |  |  |
| Software Requirements (optional) | Describe options of software scheduling capabilities for parallel execution of unit operations on different or same experiment. |  |  |
| Software Requirements (optional) | Describe anticipated training requirements to familiarize new users for adoption of platform with limited support. |  |  |
| Software Requirements: General | Describe if self-optimized follow up experiments based on previous results are possible, within same execution or follow up execution.  |  |  |
| Software Requirements (optional) | Describe current options for an overarching parent software to control and integrate unit operations from individual/existing component platforms.  |  |  |
| Software Requirements (optional) | Describe ability of parent software and/or individual software (1) to operate with current versions of standard software and (2) adapt to version updates. |  |  |
| Hardware Requirements: General | Describe as-is dimensions of whole system (l x w x h) and alternate flexibility of system to accommodate space constraints. Please share if there are proximity constraints between individual components or other conventional lab equipment e.g., for sensitivity to electromagnetic fields.Describe dimensions of whole system (l x w x h) inclusive of potential containment system, if available. |  |  |
| Hardware and Software Requirements | Please describe step-by-step operations for end-to-end execution of solubility measurement for (a) organic process-relevant and (b) aqueous bio-relevant media. |  |  |

## 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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