

REQUEST FOR PROPOSAL

**ETC Data Curation Workbench**

July 21, 2023

Enabling Technologies Consortium

Request for Proposals

Table of Contents

[1 Introduction 3](#_Toc140160508)

[1.1 About Enabling Technologies Consortium (ETC) 3](#_Toc140160509)

[1.2 Request for Proposals 3](#_Toc140160510)

[1.3 Disclaimer 3](#_Toc140160511)

[1.4 RFP Contact Information 4](#_Toc140160512)

[1.5 Anticipated Time Frames for Evaluation and Selection Process\* 4](#_Toc140160513)

[1.6 Project Scoping and Project Execution 4](#_Toc140160514)

[1.7 Intellectual Property 4](#_Toc140160515)

[1.7.1 Existing Intellectual Property 5](#_Toc140160516)

[1.7.2 New Intellectual Property 5](#_Toc140160517)

[2 Project Information 5](#_Toc140160518)

[2.1 Possible Project Sponsors 5](#_Toc140160519)

[2.2 Description 5](#_Toc140160520)

[2.3 Requirements 6](#_Toc140160521)

[2.3.1 Necessary Hardware and Software Requirements 6](#_Toc140160522)

[2.3.2 Optional Hardware and Software Requirements 8](#_Toc140160523)

[2.3.3 Availability Requirements 8](#_Toc140160524)

[2.3.4 Licensing Requirements for Commercialized Product 8](#_Toc140160525)

[3 Criteria for Evaluation 9](#_Toc140160526)

[4 Respondent Profile 9](#_Toc140160527)

[4.1 Company/Organization Information 9](#_Toc140160528)

[4.2 Primary Contact Person 10](#_Toc140160529)

[4.3 Company/Organization Overview 10](#_Toc140160530)

[4.4 Parent Corporation and/or Subsidiaries 10](#_Toc140160531)

[4.5 Summary of Expertise 11](#_Toc140160532)

[4.6 Standards Certifications 11](#_Toc140160533)

[4.7 Goals and Strategic Vision 11](#_Toc140160534)

[4.8 Miscellaneous 11](#_Toc140160535)

[5 Company/Organization Response to RFP (*to be completed by RFP respondent)* 11](#_Toc140160536)

[5.1 Proposal 12](#_Toc140160537)

[5.2 Functional Requirements & Specifications 12](#_Toc140160538)

[5.3 Estimated Timeline 16](#_Toc140160539)

[5.4 Estimated Project Cost 16](#_Toc140160540)

[5.5 Commercialization and Support 16](#_Toc140160541)

# 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 Proposals

Publication of this RFP (Request for Proposals) is the first step by ETC to solicit interest in collaborating on the project titled “**Data Curation Workbench.**” The information collected during the RFP process along with subsequent interviews will be used for evaluation purposes with the goal to select a third-party collaborator to engage with on this project.

## Disclaimer

The contents and information provided in this RFP are meant to provide general information to parties interested in developing the project “**Data Curation Workbench**”. 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 RFP, please note the following:

* This RFP is not an offer or a contract
* Responses submitted in response to this RFP become the property of ETC
* Respondents will not be compensated or reimbursed for any costs incurred as part of the RFP process
* If ETC receives and responds to questions from RFP 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 RFPs 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 RFP responses but agrees not to publicly distribute RFP responses outside of ETC or share RFP responses with other respondents.
* ETC is not obligated to contract for any of the products or services described in this RFP
* 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 RFP at any time

## RFP 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](mailto:info@etconsortium.org)

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

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

Issue RFP August 21, 2023

Questions on RFP due September 6, 2023

ETC responds to any RFP questions September 27, 2023

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after September 27, 2023 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 * AstraZeneca * Biogen * Boehringer Ingelheim * Bristol Myers Squibb * Eli Lilly & Co * Merck * Pfizer * Zoetis Pharmaceuticals |

## Description

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| The ETC Analytical Purification Working Group (WG) is seeking a system that impacts current challenges with managing data, including, but not limited to   * Accessing internal and 3rd party data * Leveraging “big data ontologies” to relate disparate data sets * Build reports, dashboards or other “artifacts” which advance the scientific process * Build data integrity into “artifacts” that ease the burden for emergency data integrity reviews * Notify artifact creators and other pertinent contributors of data changes   The picture below articulates the groups vision for electronic data. The content of this document emphasizes the significant unmet needs in the 3 right columns. |

## Requirements

### Necessary Hardware and Software Requirements

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| ***Design & Engagement Constraints***   1. Solution must extend full range of functionality in Windows and iOS 2. Solution must demonstrate a design that allows for the integration of multiple capability modules for the laboratory environment. Data Capture, Curation, Collection, Visualization and Final Information Assembly. 3. Solution modules must integrate with existing enterprise collaboration platforms 4. Confirm an open and modular architecture for data storage and integration. 5. Solution must demonstrate sufficient flexibility in security levels and system access. The system must meet all regulatory requirements for security and audit trails. 6. Solution must not require heavy client software installation or the use of client emulation. 7. Solution/Platform must allow for use by 3rd party collaborators. Some partners may be limited by size or budget, solution must be accessible and sustainable for such organizations. 8. Solution must demonstrate the ability to integrate with other related scientific modules to be further defined by the WG (i.e., Notebook, Visualization) 9. Solution must seamlessly interface with common business productivity tools including MS365 components, visualization platforms, meeting and collaboration tools 10. Solution must include the ability to quickly build, secure, enable, disable and integrate new modules (user interfaces) that meet emerging standards for low-code/no-code application development   ***Data Acquisition, Processing & Curating***   1. Solution must allow users to bring content from multiple systems and combine them into a new artifact to drive the scientific process (i.e., reports, presentations, summaries, etc.) 2. Solution must present users with actionable data that can be used to further analyze experimental results 3. Solution must have the ability to capture, store and share “artifacts” created in the system 4. Solution must allow artifacts to be promoted or shared 5. Solution must allow artifacts to be deleted by appropriately permissioned users 6. Solution should notify users if data used in an artifact are changed by the source system 7. Solution should document a “chain-of-custody” that shows where data originated from and its path into the currently viewed artifact 8. Solution must enable the creation of user enabled visualizations and reports 9. Solution should include a laboratory wearable solution to capture video and images with minimum effort, working with common laboratory safety gear.   ***Scientific Notation & Laboratory Journaling***   1. System must have the concept of an electronic container for note-taking where users can capture experimental information 2. System must allow the user to enter metadata about the experimental record 3. System must allow users flexibility with the type of content to include within the record 4. System must contain a “keystroke” audit trail so that previous version/edits cannot be obscured 5. System must support configurable workflows for peer review, sing-off and/or approvals   **Engagement Requirements**   1. Collaborate with the WG to finalize project scope. 2. Selected respondent must partner with WG subject matter experts to finalize key user stories and establish and demonstrate an understanding of these scenarios. |

### Optional Hardware and Software Requirements

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| * System should allow Integrated devices (i.e., wearables, mobile phones, tablets) to capture information and move content into other software modules within the ecosystem (i.e., notebook, analytics, reporting) |

### 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. |

### 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. |

# Criteria for Evaluation

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| The ETC will evaluate the responses to this RFP 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 RFP as evidenced by the RFP response and presentations made to ETC. * Provide a cost-effective solution that is compatible with the goals of the project (see Section 5.4). * Demonstrate domain expertise and an ability to work collaboratively with the ETC in development of a data curation workbench. * 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 RFP. * 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 RFP. 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

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

## Proposal

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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## 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:

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| 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 |
| --- | --- | --- | --- |
| Design & Engagement Constraints | Solution must extend full range of functionality in Windows and iOS |  |  |
| Design & Engagement Constraints | Solution must demonstrate a design that allows for the integration of multiple capability modules for the laboratory environment. Data Capture, Curation, Collection, Visualization and Final Information Assembly. |  |  |
| Design & Engagement Constraints | Solution modules must integrate with existing enterprise collaboration platforms |  |  |
| Design & Engagement Constraints | Confirm an open and modular architecture for data storage and integration |  |  |
| Design & Engagement Constraints | Solution must demonstrate sufficient flexibility in security levels and system access. The system must meet all regulatory requirements for security and audit trails. |  |  |
| Design & Engagement Constraints | Solution must not require heavy client software installation or the use of client emulation |  |  |
| Design & Engagement Constraints | Solution/Platform must allow for use by 3rd party collaborators. Some partners may be limited by size or budget, solution must be accessible and sustainable for such organizations |  |  |
| Design & Engagement Constraints | Solution must demonstrate the ability to integrate with other related scientific modules to be further defined by the WG (i.e., Notebook, Visualization) |  |  |
| Design & Engagement Constraints | Solution must seamlessly interface with common business productivity tools including MS365 components, visualization platforms, meeting and collaboration tools |  |  |
| Design & Engagement Constraints | Solution must include the ability to quickly build, secure, enable, disable and integrate new modules (user interfaces) that meet emerging standards for low-code/no-code application development |  |  |
| Data Acquisition, Processing & Curating | Solution must allow users to bring content from multiple systems and combine them into a new artifact to drive the scientific process (i.e., reports, presentations, summaries, etc.) |  |  |
| Data Acquisition, Processing & Curating | Solution must present users with actionable data that can be used to further analyze experimental results |  |  |
| Data Acquisition, Processing & Curating | Solution must have the ability to capture, store and share “artifacts” created in the system |  |  |
| Data Acquisition, Processing & Curating | Solution must allow artifacts to be promoted or shared |  |  |
| Data Acquisition, Processing & Curating | Solution must allow artifacts to be deleted by appropriately permissioned users |  |  |
| Data Acquisition, Processing & Curating | Solution should notify users if data used in an artifact are changed by the source and allow the artifact to be updated |  |  |
| Data Acquisition, Processing & Curating | Solution should document a “chain-of-custody” that shows where data originated from and its path into the currently viewed artifact |  |  |
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| Scientific Notation & Laboratory Journaling | System must allow the user to enter metadata about the experimental record |  |  |
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| Scientific Notation & Laboratory Journaling | System must contain a “keystroke” audit trail so that previous version/edits cannot be obscured |  |  |
| Scientific Notation & Laboratory Journaling | System must support configurable workflows for peer review, sing-off and/or approvals |  |  |
| Engagement Requirements | Collaborate with the WG to finalize project scope |  |  |
| Engagement Requirements | Selected respondent must partner with WG subject matter experts to finalize key user stories and establish and demonstrate an understanding of these scenarios. |  |  |
| Optional Requirements | System should allow Integrated devices (i.e., wearables, mobile phones, tablets) to capture information and move content into other software modules within the ecosystem (i.e., notebook, analytics, reporting) |  |  |

## 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;**
* Historically ETC members provide $20,000-$40,000/company/year for projects undertaken by ETC resulting in budgets up to $450,000 for a multi-year project.
* 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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