

REQUEST FOR INFORMATION

**Colonic Absorption: Preclinical Characterization for Better Translation to** **Humans**

February 24, 2021

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 “**Colonic Absorption: Preclinical Characterization for Better Translation to Humans.”** The information collected during the RFI 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 “**Colonic Absorption: Preclinical Characterization for Better Translation to Humans.”** The successful respondent selected by ETC at either the RFI stage or RFP stage (if applicable) 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 February 24, 2021

Questions on RFI due March 15, 2021

ETC responds to any RFI questions April 1, 2021

Responses from potential collaborators due April 15, 2021

Invitations sent to respondents for presentation May 1, 2021

Presentation to ETC by respondents May 2021

Select finalists for RFP or select a collaborator May/June 2021

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after April 15, 2021*** ***will not benefit from full consideration and may be excluded from the selection process.***

# Project Information

## Possible Project Sponsors

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| AbbVie, AstraZeneca, Amgen, Bristol Myers Squibb, Eli Lilly, Genentech, GlaxoSmithKline |

## Description

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| The project is seeking characterization of Colonic Absorption that can facilitate implementation of Extended Release (ER) at early phase of product development and thereby impact overall timeline of development. The following project steps/milestones have been provided by ETC to aid the respondent in preparing their response; however, respondents are welcome to propose an alternative project plan to meet the project objectives. * Establishment of correlation between Caco-2 apparent permeability (Papp) data and human colonic effective permeability (Peff), using an existing data set for the Peff data (see DOI: [10.1021/mp500834v](https://doi.org/10.1021/mp500834v)) and generating necessary Caco-2 data
* Methods to consistently apply Caco-2 Papp data to make for more reliable predictions of colonic human Papp, and improvement of in-silico colonic absorption models to enable Extended Release formulations.
* Investigate the pig as an intermediate species that can be used to confirm the predictions, and further expand options for predictive assessments when molecule properties (e.g. low solubility) make the Caco-2 data generation difficult.

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## Requirements for the Project “Colonic Absorption: Preclinical Characterization for Better Translation to Humans”

### Necessary Requirements

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| Caco-2 Data - Generate Caco-2 Papp data * Data set to match the collection of human colon Peff data, with additional data if additional human data is available
* Report transporter expression levels in the cell line used, and/or generate data with inhibition of transporters.

Caco-2 Papp to human colon Peff correlation - Build a correlation between the in vitro data and the existing human colon Peff data set. See DOI: [10.1021/mp500834v](https://doi.org/10.1021/mp500834v). Use appropriate permeability markers to help build translation between labs, to enable universal application of these predictions. * Target a correlation with predictability within +-30%
* Markers should represent compounds with known/extrapolated colon permeability

Modeling - Use the human Peff data, or extrapolated Peff data based on the Caco-2 correlation, to build modeling tools for colonic absorption (using commercially available modeling software – see section 2.3.3).Pig Studies - Design and execute studies in the pig to test predictions of colonic absorption, possibly with multiple formulations (some of which may be ER), and/or with direct administration to the colon or distal small intestine (either via colonoscopy or cannulated animals).Predictive Methods for Early-Stage Screening - Develop rules-based workflow and recommended steps using knowledge gathered that would provide guidance for screening compounds extent of colonic absorption in early stages.Absorption modeling for Extended Release dosage forms - Starting with commercially accessible simulation tools and with appropriate modifications, develop screening models that utilize the data from predictive screening studies (in vitro) as inputs to predict overall absorption of ER formulations |

### Optional Requirements

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| Caco-2 Papp to human colon Peff correlation – Access to additional human colon Peff data Absorption Modeling - Leverage existing human PK data for formulations expected to involve colonic absorption if available in literature or other sources |

### Availability Requirements

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| * Information and Models from the project are usable with existing modeling software like Gastroplus or alternative tools for absorption modeling.
* Models and datasets produced and screening methods developed during this project will be made freely available for use by ETC participants and the general scientific community through an appropriate mechanism (e.g., publication in a scientific journal) without restriction.
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### Optional Availability Requirements

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| Any software solution developed as part of this project will be made available to ETC participants and the scientific community via an appropriate mechanism (e.g., open-source, commercially licensed product)1. Software will be licensed to ETC participants at no cost during (i) development and (ii) a mutually agreed beta testing period.
2. Thereafter, software will be available for licensing on a perpetual basis orsubscription basis at the option of ETC participants. The collaborator shall make available industry standard support.
3. Software shall be available for self-hosting by (or on behalf of) the ETC participants even if the collaborator elects to make a SaaS alternative available.
4. 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 the project “Colonic Absorption: Preclinical Characterization for Better Translation to Humans”
* 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.

The ETC will not provide individual feedback directly to RFI respondents beyond the status of their response to this RFI. |

# Respondent Profile *(to be completed by RFI 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 |
| --- | --- | --- | --- |
| Caco-2 data | Generate Caco-2 Papp data, reporting transporter levels, or inhibiting transporters. |  |  |
| Caco-2 Papp to human colon Peff correlation | Build a correlation between the in vitro data and the existing human colon Peff data set. See DOI: [10.1021/mp500834v](https://doi.org/10.1021/mp500834v). Use appropriate permeability markers to help build translation between labs, to enable universal application of these predictions. Access to additional human colon Peff data is a plus. |  |  |
| Modeling | Use the human Peff data, or extrapolated Peff data based on the Caco-2 correlation, to build modeling tools for colonic absorption (using commercially available modeling software). Leverage existing human PK data for formulations expected to involve colonic absorption if available in literature.  |  |  |
| Pig studies | Design and execute studies in the pig to test predictions of colonic absorption, possibly with multiple formulations (some of which may be controlled release), and/or with direct administration to the colon or distal small intestine (either via colonoscopy or cannulated animals). |  |  |
| Predictive Methods for Early Stage Screening | Develop rules-based workflow and recommended steps using knowledge gathered that would provide guidance for screening compounds extent of colonic absorption in early stages. |  |  |
|  Absorption Modeling for CR dosage forms  | Starting with commercially accessible simulation tools and with appropriate modifications, develop screening models that utilize the data from predictive screening studies (in vitro) as inputs to predict overall absorption of CR formulations |  |  |

## 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:

* 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;
* For academic or non-profit partnerships, any monetary contributions by ETC will be for the total project costs, inclusive of indirect costs.

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.

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