ENABLING TECHNOLOGIES CONSORTIUM – VENDOR COLLABORATIONS FAQ

DEVELOPING AN RFI/RFP RESPONSE:

- ***Are multiple submissions per vendor allowed?***
    - Yes, a vendor can provide multiple submissions if the proposals are significantly different. Each proposal will be reviewed separately and scored on its own merits.
- ***It is mentioned "possible" partners in section 2.1: when will be decided which partners will be part of the project? How many partners are usually taking part?***
    - The final number of ETC Member Participants will be determined when the project Charter is drafted. Each of the partners will indicate their willingness to participate in the project based upon the SOW and recommendations from their representatives on the project team. Historically we have had projects with 4-10 ETC members participating.
- ***In section 2.3.4. it is mentioned that "Software will be licensed to ETC participants at no cost during (i) development and (ii) a mutually agreed beta testing period." Which software is mentioned by that? We understand the instruments consists of both soft- and hardware.***
    - This is a general statement referring to any software developed as part of the project or required to participate in the project (e.g., data capture or instrument control software) to evaluate beta/prototype units. It does not include downstream or upstream software that isn't directly related to the project.
- ***What is the expectation in 5.1.? What shall be part of the proposal?***
    - This is where you would enter your proposal information. It is free form to allow you to enter what information you deem relevant to your proposal.
- ***Section 5.2: The chart on page 12 is empty.*** **Which Functional Requirements and Specifications checklist are meant here?** ***What kind of Features / Requirements have to be responded and rated there?***
    - That chart is meant to be filled out by the respondent using the requirements/specifications in Section 2.3. This allows you to break up or group the requirements as necessary to tailor your response to your particular proposal.
- ***Section 5.3: Are you referring to the timeline until a fully developed and commercial product?***
    - No, this is timeline for the project and when specific milestones/deliverables would be met. Any predictions or thoughts on a commercialization timeline would be provided in 5.5.
- ***Section 5.4 Estimated Project Cost: What kind of costs must be listed here? Do we have to specify an hourly rate and the expected expenditure of time for the development and creation of a prototype? Or do we have to estimate the total project cost until the commercialization of the product? What kind of detail information are required here?***
    - The costs are the costs to deliver what you are proposing to deliver in response to the RFI/RFP. You should provide information related to the total project cost, the fixed price cost to be charged to ETC, and any investment your company is putting toward the project in US Dollars. It is important the cost to ETC is a fixed price to provide the ETC members budget certainty. For the purposes of theRFI/RFP you can give a price range but ETC will require a fixed cost to be determined through scoping and finalization of a Statement of Work before the project is started.

ETC PROJECT PROCESS & TIMELINE

- ***We discovered your project and was hoping you could clarify the timeline. I interpret this document to say only the questions we have on the project specification are due on [specified date on RFI/RFP], clarification on these questions will be submitted by [specified date on RFI/RFP] and with these answers our finalized project proposal in this fillable PDF is due on [specified date on RFI/RFP]. Did I interpret that correctly?***
    - o Your interpretation is correct. We are asking people to submit any questions they have to ETC by the first date listed on the RFI/RFP. All questions received will be discussed with the team and answers provided back by date specified on the RFI/RFP. All questions received will be anonymized and posted on the project page of our website (https://www.etconsortium.org/projects) so everyone can benefit from the information. The deadline for responses is specified on the RFI/RFP and on specific project pages on our ETC website. The fillable form has been provided to aid in your response but feel free to include any additional documents to support your response as well.
- ***What is the expected delivery timeline and what is the expected duration of the project?***
    - o The delivery timeline will be discussed in detail after a collaborator has been selected, but please include a proposed timeline in your response.
- ***Could you advise the process and timeline following the submission of RFI/RFP?***
    - o Following submission of RFI/RFP responses, the team will evaluate proposals and send further questions for clarification as needed before selecting a collaborator. A virtual or an in-person scoping workshop may also be scheduled with the selected vendor to further refine the proposal and project.
- ***After the collaborator has been selected, what shall the timeline for the development look like?***
    - o In general from the time the RFI/RFP is released until project start is approximately 6-12 months but that can be faster or slower depending on the project. The timeline depends on a lot of factors but primarily driven on how quickly a Statement of Work (SOW) can be created and agreed upon by both parties. Once that process has made enough progress the ETC Secretariat will work with the collaborator on the Development
- ***What is the estimated duration of the project?***
    - o The project duration should be proposed by the 3rd party, based upon the time they believe they need to complete the project. Projects in ETC typically last 1-3 years with options to execute additional work through new SOWs after the completion of the initial SOW.
- ***When is the anticipated project start date?***
    - o This is unknown at this stage in the process.   ETC may decide to scope a project with one of the I respondents or issue a second request.   This RFI/RFP process is scheduled to conclude on the specified due date for responses on the RFI/RFP.
- ***Once the project has started how much time will the ETC and sponsor participants have to engage on the project on a monthly basis?***
    - o Individuals from ETC will be comprised of representatives from ETC member companies participating in the project. The frequency and need for meetings between ETC participants and the collaborator will be determined in the project plan. Typically ETC

and the collaborator meet either monthly or quarterly at a minimum to get product updates from the collaborator, but more frequent meetings are possible if needed.

- **Is the Enabling Technologies Consortium open to accepting a phased approach with predefined deliverables and financial disbursements?**
  - Yes, the Enabling Technologies Consortium is open to a phased project approach.

ETC ROLES, ENGAGEMENT, AND COLLABORATOR QUALIFICATIONS

- **Which role will the ETC have during the development project?**
  - Depends on the project but typically the ETC members participating on the project will provide subject matter experts and/or scientists to serve as a resource to the collaborator, providing support, data, samples, insights, testing and evaluation of deliverables, provide feedback, etc.
- **Who would establish priorities between the sponsors?**
  - ETC members on the project and the collaborator will work together to scope the project priorities and capture these in a SOW, which will specify the project deliverables, timeline, payment schedule, fixed cost in US dollars to ETC, etc.
- **Does ETC expect a company to lead the proposal or it is okay for an University-based team to lead?**
  - For most projects ETC welcomes responses from any interested parties, including a University-based team. The ETC is open to either University or company led teams, and it is not an expectation that this project would be led by a company based team. However, if the specified goal of the ETC project is to develop commercial technology, University-based teams are strongly encouraged to include in their proposal their plans for making the technology commercially available.
- **Are joint proposals considered from academic institutions, or is it preferred to have a single institution lead and have a collaborator indicated from another institution?**
  - Joint proposals from multiple academic institutions and/or commercial organizations will be considered. However, for keeping the execution of the collaboration agreement the simplest the preference is that one institution/organization acts as the primary and have the other be a collaborator/subcontractor. If this is not possible, ETC will provide a multi-way collaboration agreement.
- **We as an engineering company are also partnering with universities for joint developments. Can we include them in our proposal or do we need to apply as a single organization?**
  - Yes, you can include them in your proposal. ETC recommends/prefers that the collaborator treat their partner(s) as subcontractors/service providers so that the agreements and negotiations are only between ETC and the collaborator, with the collaborator responsible for ensuring that their partner(s) adhere to the terms set forth in the agreement. However if this isn't possible, we can contract with multiple parties.
- **Can individual project sponsors collaborate with commercial vendors in this project?**
  - Yes, individual project sponsors (i.e., members of ETC) are welcome to collaborate with commercial vendors outside of an ETC project if they so choose to. The benefits for conducting a project within ETC vs. multiple, individual project sponsors include: collective requirements, single development agreement vs. multi-party agreement, sponsor funding dollars go farther since costs are split over multiple sponsors.
- **Can we contract out development of sub systems or work with external experts to facilitate rapid development?**

- o Yes. You can sub-contract out any of the work for a project with ETC. ETC will execute the contract with the 3rd party selected for the project. The 3rd party should include it its budget request to ETC any project costs to be paid to the sub-contractor. The 3rd party would be responsible for payments to the sub-contractor, any delays, or issues relating to the subcontracted work.

- **What are the collaborating partner capabilities? Is that something we should discuss with individual collaborators or will that be decided after proposal submission? What role can the partners play (i.e., piloting, testing, developing, analyzing)?**
  - o In general, ETC members participating on this project will be available to provide Subject Matter Expertise to support the collaboration through piloting, testing, helping with development, analyzing data, providing feedback, etc. The exact details and support requests from ETC members should be included in the proposal and can be discussed in more detail as part of the proposal evaluation process. Note, typically any samples provided by ETC are non-proprietary, off the shelf samples; if a vendor requires or an ETC member wishes to provide proprietary samples for evaluation, that will be handled and discussed with the individual members as part of the project scoping process.

- **When will the project sponsors be formalized? Will we have direct communication with the project sponsors during the work?**
  - o Typically, the project sponsors are known during the scoping phase with the collaborator but will be formalized at the time the internal ETC Project Charter is sent for signature. For all projects, the 3rd party collaborator has regular meetings with the project sponsors, usually on a monthly or quarterly basis in order to report on progress, receive input/feedback, and get additional information.

- **Can my company become a member of ETC?**
  - o ETC membership is limited to companies engaged in the development of new chemical or molecular entities for the prevention, diagnosis, or treatment of disease with at least one active Clinical Trial Application.

- **Does the ETC group have connections within the ICH Council, or have any crossover**
  - o Active participants in ETC do not have direct interactions with the ICH. However, individuals within ETC member companies can be identified to facilitate an interaction if appropriate.

PROJECT FUNDING, BUDGET, & SPONSORS

- **Is the selected project going to be funded by ETC? and if so, what proportion of the total costs?**
  - o There is no guarantee that ETC will fund any given project. Once a project is scoped out and a Statement of Work (SOW) created by the selected 3rd party in consultation with the ETC project team, the ETC members will determine if there is sufficient interest to fund a particular project and meet the requested funding amount. As for the proportion of the total costs, there is no predefined fraction. The funding provided by ETC to a commercial vendor should be considered seed funding to supplement the total development costs, with the collaboration investing as well. It is up to the 3rd party collaborator to determine how much funding to seek from ETC.

- **What is the expected budget or estimated financial contribution from ETC for this project including any/all phases of the project?**
  - o Unless specified in an RFI/RFP, the funding available for projects isnot determined up front. Project budgets are dependent on the project proposals received along with

interest from ETC members in pursuing a particular project. Respondents should estimate the cost of the project and the total funding sought from ETC. Historically ETC funding has been in the $0 - $400,000 range spread over 1-3 yrs. but there is no hard limit on the amount of funding. Once a project is scoped out and a Statement of Work available, the ETC members will determine if there is sufficient interest to fund a particular project and meet the requested funding amount. The funding provided by ETC to a commercial vendor should be considered seed funding to supplement the total development costs, with the collaboration investing as well since with most projects, all commercialization rights will reside with the collaborator and ETC will not assume ownership of any intellectual property (IP) developed by the collaborator or expect royalties from future commercial sales.

- ***Is there a limitation or range to the overall allowed budget?***
  - o No, the budget for this project has not been set and will be based upon the selected proposal and the interest of ETC members to fund a given proposal
- ***Are there any limitations on what the RFP funding can be spent on (i.e., salaries, equipment, etc.)?***
  - o There are no official limits on what the RFP funding can be spent on other than expenses should be related to the project. However, ETC likely will not fund line items related to patent or trademark filings, marketing, or other expenses not directly related to technology development or the project deliverables.
- ***"Direct costs" only reduces the scope of what we can do, as our budgeting typically includes indirect overhead as we work with students and have facilities. Is there any way to include indirect costs in the budget?***
  - o A respondent may include "Indirect costs" in their budget. If a proposal is selected, ETC may further negotiate the total costs to align with available funding being provided by ETC members. Please note that "Direct Costs" in the ETC context includes items such as faculty salaries, postdoctoral and student fellowships, supplies, equipment, travel, etc. It is important that whatever budget proposed represents the final fixed cost to ETC inclusive of any indirect costs.
- ***Can you let us know the funding range (ballpark) for academic work on such a project?***
  - o The budget will be based upon the selected proposal and the interest of ETC members to fund a given proposal. If the available budget is less than what was requested, ETC will look to negotiate the costs to align with the available budget; this negotiation could include reduction of direct costs, indirect costs or scope of the project. Respondents are encouraged to provide a budget that will satisfy the requirements and requested deliverables specified in the RFP.
- ***Is there a preferred cost-sharing percentage?***
  - o There is not a predefined or preferred cost sharing percentage dictated by ETC. As stated in the RFP, any funding provided by ETC should be considered seed funding towards the project with the collaborator investing as well. The respondent is responsible for determining how much they wish to invest in the project.
- ***Since the overall budget and cost-sharing is proposal specific, to justify the amount of cost sharing with ETC, the market potential of the proposed technology is required. If the development is successful what level of commitment from ETC members can be expected? i.e., how many "units" are the ETC members expected to require at the end of the project. What interest would you expect outside of the consortium?***

- o Our antitrust guidelines prohibit ETC's members from sharing their purchasing information (i.e., pricing, commitments) with ETC so we cannot comment on this nor will ETC seek to gather this information. Furthermore, ETC will not commit to the purchase of systems by its members following the conclusion of any project. Simply stated, each of our members makes its own purchasing decisions within their companies, with no influence or direction provided by ETC.
- o The members of ETC who are participating in this project (listed in the RFI/RFP document) are the companies that initiated this project and could be potential customers of the commercial solution. However, ETC does not have insight into the information you are requesting, as this is considered market research and as stated above is something that is outside our scope of activities.
- o With regards to interest outside the consortium, given that the projects are based upon the collective needs of the pharmaceutical community it is the goal for the technology derived from any ETC project to be broadly applicable to that community, not just those companies participating in the collaboration. Vendors are encouraged to reach out to any company they wish to conduct their own market research based on the individual input that company may choose to share.

PROJECT SCOPING AND DEVELOPMENT

- **The project requirements presented to date are very high-level, how does the ETC team and sponsors envision getting to a detailed set of requirements over time?**
  - o The RFI serves to survey the landscape of potential solutions to the set of requirements contained within. If this project goes forward directly from the RFI phase to selection of a collaborator, then the scoping phase will be used to get to the detailed set of requirements and ultimately drive the creation of an SOW to deliver those requirements. Alternatively, ETC may choose to release a more detailed RFP which will contain more refined project requirements to ultimately choose a collaborator and entered the scoping phase.
- **I noticed that the RFI states that the goal is to create a prototype, I imagine if a product already exists on the market then this would be acceptable and probably favorable to the project sponsors – could you confirm? Pending some sort of evaluation of course.**
  - o The team is willing to receive a proposal for a product currently on the market. Existing capabilities should be indicated for each requirement in your response
- **If there is an existing commercial product that meets all the high-level requirements identified will the project proceed?**
  - o Highly unlikely but given the number of ETC members involved in creating this RFI, it is likely that existing commercial solutions have one or more gaps in their current capabilities and are unable to 100% satisfy the requirements set forth in this RFI. However, if an existing commercial product is identified that satisfies all the requirements specified then the RFI will have served its purpose and identified a commercial solution.
- **Is it intended that the selected partner should supply a development instrument to the consortium? If this is the case, where would this instrument be situated?**
  - o Yes, a development instrument to allow ETC members on the project to test and evaluate the technology will likely be needed. Making the instrument available to ETC members for testing can occur in several ways: 1) shipped and setup onsite at the each

of the various companies; 2) setup in regional locations allowing companies to come onsite to test; or 3) system setup at your facility for ETC members to test onsite or send samples for testing.

- ***Would we be able to analyze pharmaceutical samples from the project sponsors to compare analyses between detectors?***
  - o Access to proprietary compounds is likely to be company dependent. Certain companies will allow this with a suitable CDA in place, but in some cases, companies would prefer to assess the analytes on site with a beta-test system and share the data back with collaborator. This will be confirmed prior to commencement of any project.
- ***If so, would ETC share analytical data for marketing and white papers? Can we expect to co-author journal articles?***
  - o The sharing of analytical data for marketing and white papers is possible but will be project dependent, especially if the project team is looking to present/publish on the project. These requests will be handled on a case-by-case basis. 3rd party collaborators will be invited to co-author/co-present on the project as well.
- ***How does ETC envision the deployment and adoption of this solution after completion of a successful project?***
  - o The general intent for every ETC project is that the output eventually results in a new commercial product offering to the scientific community. Through collaboration with multiple ETC members providing collective requirements and feedback to the 3rd party collaborator the goal is that the resulting technology will be fit for purpose and readily adoptable by the industry.
- ***Should the developed system get commercialized, will there be any preference given to industrial partners involved during the development and prototyping stage to produce the final product? Would this change depending on the partners' involvement, i.e., if they contribute in-kind or financially? The IP and know-how raised during the project could be critical for successfully commercializing the system to make it available to ETC member companies.***
  - o ETC has no preference on industrial partners involved during the development and prototyping stage to produce the final product regardless of ETC's contribution. It will be up to the collaborator to decide how the final product will be produced. Typically any IP developed as part of the project would reside with the collaborator unless any ETC member company IP was included in the project in order to provide the collaborator the greatest flexibility to bring the output of a project available to the greater scientific community as a commercial product offering.
- ***What is the expected level of post project solution uptake?***
  - o ETC does not have insight into the information you are requesting, as this is considered market research and something that is outside our scope of activities. The members of ETC who are participating in this project are the companies that are interested in this project and would be potential customers of the commercial solution.

COMMUNICATION AND LEGAL (CONFIDENTIALITY, IP, & COMMERCIALIZATION)

- ***What is the internal project Charter?***
  - o The internal project charter is the agreement signed by all ETC members participating in the project. It provides details about the project (e.g., timelines, costs, deliverables),

budget requested, terms/conditions negotiated with the 3rd party. The Charter serves as the basis for the Development Agreement and Non-Disclosure Agreement between ETC and the 3rd party collaborator. The Charter, Development Agreement and Non-Disclosure Agreement all use template language which was been reviewed and approved by ETC members to accelerate the process.

- ***What confidentiality clauses will be put in places to prevent any risk of any details of a bidder's information being communicated with other bidders?***
    - o The RFI/RFP which states that "Responses to RFI/RFP 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/RFP responses but agrees not to publicly distribute RFI/RFP responses outside of ETC or share RFI /RFP responses with other respondents."

- ***What confidentiality clauses will be put in place to prevent details of the project once it has commenced being shared outside of the consortium members?***
    - o For projects done in collaboration with ETC, we typically execute our standard NDA with the 3rd party.

- ***Can you supply the ETC's Development Agreement and Non-Disclosure Agreement accelerator templates please?***
    - o These will be supplied to the 3rd party is chosen for the project at the appropriate time.

- ***Could we ask funding from ETC/participant companies to secure and/or access any IP needed for a project?***
    - o Any funding requests should be included in the proposed budget.

- ***If the development meets its intended goals, are the techniques developed usable by other vendors?***
    - o It depends if the developed techniques are considered intellectual property or not. Any IP developed by the collaborator as part of the project will reside with the 3rd party collaborator and it is up to the collaborator to decide how to license this IP unless licensing predetermined during scoping phase and stated in the Statement of Work (SOW) and/or development agreements. It should be mentioned that ETC in conjunction with the 3rd party collaborator typically publishes the output of projects to peer reviewed journals which will contain the techniques used in the project. These manuscripts are reviewed and approved by all parties before submission.