Trials@Home RFP Q&A - 12 Jan 2021

➔ **https://trialsathome.com/request-for-proposal/**

Q: Is the webinar recorded and will the slides be available?
A: Yes the webinar was recorded, you can find the recording and download the slides here: https://trialsathome.com/webinars/

Q: Are the following types of patient interfacing technologies in the scope of the RFP?

- Blood glucose testing
- Continuous blood glucose monitoring
- Insulin injections, tracking injections
- Other wearables and measurement devices?

A: yes, a lot of these are in the scope of the RFP, you can find the details of the scope in the RfP, you have to explore the requirements of the different BBB. You can download the full RfP pack here or expand the various BBB items on the webpage. More items can be added in the future once the pilot setup has been finalised.

Q: Regarding the structure of answering the proposal: Is it expected to slice the answer per BBB profile (e.g. Setup and Design) and provide as many proposals as BBB Profiles we would like to participate? Or do you provide a global answer mentioning on which BBB profile we would like to contribute?
A: We need to understand what parts of your proposal belong to which BBB, so you can do it in one big document mentioning for each line item to what BBB it belongs or break it down in different documents per BBB. For reviewing purposes, it's important that we can identify to what part of the RfP you're responding.

Q: Tech solutions: We understand you have already selected few technology solutions, can you please share more information on these solutions?
Is there a list or definition of the things that are "missing" on the ClinPal platform and the additional solutions need to provide to provide the full solution?
A: ClinPal, as a partner in the Trials@Home project, has been selected to cover part of the technological needs to create an end-to-end remote trial, but they don't cover everything. The identified technology gaps - that ClinPal does not cover - are outlined in the RfP. Some other – traditional/operational – needs are not covered in the RfP (eg CRO, Home nursing, …), because they are either covered by other partners in the consortium or will be purchased separately. So, all the current technological needs are covered in the RfP, we don't need you to identify missing pieces or provide proposals for items not covered in the RfP. Please also note that the RfP is a large wish list, we will not necessarily buy all the technologies mentioned, we aim to create a workable technology package within the constraints of the project.

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Q: Do suppliers get extra-points for addressing more than one BBB? Can candidates use partners to provide some of the BBBs (eg, IMP supply) or is the expectation to have it all in-house?
A: It can indeed be seen as a benefit if you can cover more than one BBB as we like to avoid contracting "a thousand" different parties and thus avoid complexity. The more integrated everything is, the better the whole package and data flow will be. If you can pre-assemble the puzzle (to some degree) for us by contracting a third party it can help us reduce the complexity, but we do ask you to mention the third parties. Julius Clinical, the contracted CRO partner, has a complete set of SOPs in place that will be governing how activities are executed and overseen.

Q: In the detailed tech package slide are those detailed components outline things NOT provided by ClinPal?
A: On the slide we show the full end-to-end trail activity model, provided by ClinPal or not. ClinPal covers some of these components, the rest of the technical needs is covered in the RfP

Q: Is there a preference for EU companies over non-EU companies?
A: Yes, preference will be given to EU companies, but non-EU companies will not be excluded if the technology they provide is what we're looking for and that solution isn't available from any of the EU applicants. This decision is driven by the funding model of the project, the money to project has received is from the IMI and they are funded by the European Commission.

Q: It appears prior clinical trial experience is required for the IMP supply and intervention/follow up building blocks. Is this also a requirement for the operations and coordination, telehealth, and patient engagement blocks?
A: Yes, that is preferred. We would favour of-the-shelf solutions as developing over a one-year period will add unnecessary stress to the project and possible delays that we can't afford. Prior experience and of-the-shelf solutions can therefore be prioritised.

Q: When is the First Patient In date?
A: Our goal – according to our timelines – is April 1st 2022 for First Patient In Date. 2021 will be used to assemble the package, test it, find the gaps.

Q: Which Pharma is involved for this trial?
A: You can find the full list of participating pharma partners on the project website: https://trialsathome.com/about-us/

Q: Will it be a phase 1,2,3 or 4 trial?
A: It will be a phase 4 trials, the chosen IMP is already on the market

Q: How big will the trail be? Which regions, how many centers?
A: We're developing the study at the same time as the technology package, so not everything is set in stone yet, but we're currently aiming at conducting the study in 10

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European countries, with an overall sample size of 1000 patients involved. These main assumptions are also outlined in the RfP documentation on the website. You can download the full pack of documentation at the bottom of the webpage that outlines the RfP (link above).

Q: How much budget is available for external technology providers?
A: There is a sizable budget available for the technology package. The entire project budget is 40mil EUR, half of that are actual euros provided by IMI, the other half are in kind contributions by the EFPIA partners. A good amount of the actual euros is set aside for the technology package and innovative services and we feel that budget is large enough to cover all of our needs. We will evaluate and negotiate the cost of all the items and make sure we can fit it all in the foreseen budget.

Q: You talked in the RFP about conversational AI. What about validation with this technology?
A: If that part of the technology is used in trial, so after consent, it becomes a clinical trial system and thus it needs to be compliant with all of the regulations, it needs to be validated according to the computer system expectations. If the technology is used outside of the trial (prior to consent) it needs to be evaluated case by case. Validation expectations are what you would expect in a normal clinical trial.

Q: Is the "Central Pharmacy" a community pharmacy or a hospital pharmacy or something else?
A: There are multiple possibilities, we're in a creative environment, we want to ensure that whatever it is that you're proposing is something that you can back up in terms of its ability to function and function correctly across all the EU member countries that will be participating, so the central pharmacy can be a university, a commercial community pharmacy or a central depot that distributes to each country. Here again, if you have an of-the-shelf solution, that will give you an advantage, but we're open to creative and innovative solutions too that's why our visions are quite high-level, leaving plenty of room for innovative solutions.

Q: Does the scope of the RFP depend on the status of COVID-19 (i.e. will there need to be more robust remote functionality if the disease infection rates and lockdowns continue)?
A: Whatever happens with COVID-19 won't change the scope too much given we want to develop an end-to-end fully remote technology package to run a fully remote trial, and that's what the RfP is for. COVID-19 might impact the traditional or hybrid arm but won't affect the remote arm that much. So, the Pilot Study might be changed, but not the remote arm.

Q: Could you please elaborate if experience in diabetes is favourable or mandatory for this RFP?
A: Experience with remote diabetes monitoring would be of great value. However, the innovation aspect is what we like to see, so bring your creative solutions to the table but remember that by January 2022 everything needs to be integrated and validated, ready for execution.

Q: Data acquisition & processing Block: Which specific standards are you expecting this platform to be compliant with? For example FHIR Common Data Model etc ... Are you tight to any particular data platform?

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A: We consider several data relevant standards like FHIR, CDISC and others. Data exchange between different modules is of high importance. The compliance to standards will be one criteria considered in the assessment. In general we will look at the overall package suggested. As ClinPal is serving as the basic solution, it might be helpful to check on their website which interfaces they provide

Q: You mentioned that the IMP in this pilot is in an injectable. Is this self-administered by the patient, or performed by the home health nurse/coordinator?
A: It's self-administered. Home nursing can be foreseen if a patient needs to be trained.

Q: If a vendor doesn't meet one knock-out criteria and no one else does meets these criteria, are we still "in" if we meet the other criteria? I.e., if we meet most criteria is still worth to submit a request?
A: It will depend on the case, if you're not sure, we suggest you submit anyway and see what happens

Q: We specialize in remote monitoring of patient safety using extraction of their medical records, which compliments this model, however you appear to not want any safety solutions, is CLINPAL, capable of remotes safety monitoring and extraction of data from source?
A: The electronic data capture will be provided by ClinPal. In terms of what can be drawn into it whether eHR, wearables, all these other aspects, there needs to be a demonstration of your expertise, based on the content of the RfP, if there is something the ClinPal is not able to import or to extract, please apply and make it very clear what it is that you're proposing. ClinPal is the base solution, they will maintain most of the data, but it's not excluded that we have other data platforms post- or pre-processing of data. We need to guarantee that data can be exchanged. In the future the systems must be interoperable from both sides. Even if we use a solution that is already on the market and tested, it might need some adaption or integration work to make interoperability possible. Keep this in mind when submitting your solution. Interoperability is one option; data can also be housed and mirrored, so integration is not necessary. Keep this in mind when submitting your solution.

Q: Have you already defined the number of phase 4 Clinical Trials you want to run beyond April 2022, for how long (each), and have you identified the targeted drugs?
A: The T@H consortium will run only one phase 4 trial, for which the IMP has already been identified. The assumptions for this trial can be found in the RPF documentation. Trials that are being planned by the different consortium partners, outside of the Trials@Home collaboration are not taken into account here.

Q: Would connected sensors for remote cardio-respiratory monitoring be in the scope of this RfP?
A: Cardio-respiratory monitoring is not part of the scope of the RfP.

Q: TECH Service agreement template: Do we need to provide our comments by 15th Jan? and can you provide us word version of the document?
A: Applications should be provided by Jan 15th, including comments on the service agreement template (if applicable).

Q: How is patient confidentiality managed, as personal identifiable data will be collected by the system along with health data? Will personal and health data be stored separately?
A: Clinpal support logical separation of personal identifiers and health data through robust

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and secure role-based access control. However, I'd not that this seems unrelated to Clinpal compatibility.

Q: Data acquisition & processing Block: Could you precise more the expected integration (Data flow) with ClinPal. For example, the eCRF function is expected into this Data acquisition block where it is more and EDC function (part of CLinPal).
A: Where data integration is required, the preference would be to employ a secure API (an authenticated web API) connection between the vendor's server and the Clinpal server to exchange data. eCRF and EDC functions are expected to be provided by Clinpal.

Q: Which TRL (Technology Readiness Level) are you expecting in the several technologies?
A: TRL is a general industry term and unrelated to Clinpal compatibility

Q: I have proposal for AI Smart Home Telemedicine based on dell technologies tools for Stroke/Heart emergencies that can be extended to IoT Diabetics and Covid.. and Also AI Smart hospital connected health based on our new Innovative Mobile AI algorithm.
What is meant by API compatible, I have now TLR 4 for AI technologies?
A: With API compatibility we mean in this concrete case that it needs to be possible to collect the IoT based data and exchange them with the a central data center (or other third party modules). Data exchange standards should be applied here and interfaces (APIs) provided. It is thinkable that a pre-processing of the IoT data takes place in a third party solution provided. In any case information needs to be exchangeable over APIs with other modules.
For technology we foresee a certain maturity to allow a proper pilot execution. Nevertheless we want to leave room for innovation. In your concrete case this would mean that for the IoT data collection infrastructure a TRL of 8 and higher should be provided. Innovation parts like some AI based data analytics might be in the status of a lower TRL.

Q: On one hand, many requested activities of the T@H platform are « excluded » from the RfP because they are already familiar and/or contracted by the T@H partners. That is fine, our core simulation technology can be included into Clinpal's user interface by calling our API, and simply displaying the result in Clinpal's interface. However this would not display our user interface at all (mobile app and web-based clinician tool), with all its added services complementing our core technology.
On the other hand, you « envision a digital platform containing multiple connected systems ». This could mean aggregating multiple user interfaces, some of them possibly partially redundant, even though all connected through a single sign-on process. In this scenario, our solution could alternatively be included as a stand-alone module of Clinpal, using our own user interface (both our mobile app for patients and our online simulator for professionals).
Which option do you prefer ? A limited API version, risking to miss some of our specific interfaces (some of them are indeed excluded from the RfP) ? Or our entire mobile app, risking to be redundant with your own app ? Or should we present both options, and we can clarify during the interviews ?
A: Both scenarios are thinkable and depend on the technology provided (fit to requirements, functionality covered etc.) as well as the activity requested. In general, it is correct that we try to achieve a high usability so the aim must be to interact with the user with a minimum of interfaces (if not one). It is thinkable that the UI of the solution is bypassed and only a direct data exchange with the base solution is foreseen but also it is thinkable that the mobile UI of the proposed solution will be used (for example in patient engagement). So, we would suggest proposing both solutions.

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Note: this document will be updated regularly based on additional questions received. Only questions received prior to the submission deadline (15 Jan 2021) will be answered.

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