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March 10, 2023

ADDENDUM #1 to the University of Florida ITN23NH-127 Clinical Trial Screening Software, scheduled to be opened on **March 29, 2023 3:00 PM** at the University of Florida, Elmore Hall Conference Room, Radio Road, Gainesville, Florida.

This addendum shall be considered part of the Contract Documents for the above mentioned **ITN23NH-127** as though it had been issued at the same time and incorporated integrally therewith. Where provisions of the following supplementary data differ from those of the original document, this addendum shall govern and take precedence. All other terms, conditions, and regulations will apply.

This addendum consists of:

Responses to technical questions and inquires submitted prior to 5:30pm, March 6, 2023.

Sincerely,

Nicola Heredia, Director
Procurement Services

Please acknowledge receipt of Addendum #1 by signing below, and returning this addendum with your proposal. Failure to include addendum with your proposal may result in rejection.

_____ _____
Signature Company Name

_____
Email Address

_____ _____
Company Address City/State/Zip

ITN23NH-127 Clinical Trial Screening Software

Q1. By external EPIC, do you mean Care Everywhere? If it is Care Everywhere, what is it used for?

A1. The reference to external records in the EMR was speaking to items scanned/uploaded into the media tab in Epic.

Q2. Does your Epic Media Tab hold any scanned reports used during the clinical trial matching process, and in what format (i.e., digital fax, digital PDF, or scanned fax)?

A2. Media tab houses documents stored in a variety of formats however scanned and native PDFs are the most common.

Q3. Which Pathology and Laboratory (LIS) system(s) would you like to interface with? Is the HL7 interface available from LIS?

A3. Pathology and LIS are both in Epic (Beaker)

Q4. What Radiology system(s) do you use? Are they HL7 compliant?

A4. Visage is the PACS viewer with a local higher performance cache and has an HL7 interface, Acuo from Hyland is the backend long term archive archive.

Q5. Is genomic data available in discrete format? Where can the data and any actual reports be accessed from?

A5. Epic genetic module is implemented so that discrete genetic data are partially available. Genomics data, including somatic, germline, and pharmacogenomic will be available in discrete format.

Q6. Who are your genomic lab companies/partners?

A6. Varying depends on clinical practices. For cancer, external labs like Tempus (and others) and UF Pathology's GatorSeq. For pharmacogenomics, majority of results are from UF Pathlab but there are results from Quest, LabCorp, and other third-party labs.

Q7. Does your data repository (data lake/warehouse) hold pertinent information for trial matching? Is the data in a discrete format? Are there any APIs?

A7. UF Integrated Data Repository is the enterprise data warehouse at UF Health. It does contain typical patient characteristics that can be used for trial matching. It's not complete. Information such as those from the genomics module is not current in the IDR. Nevertheless, these pipelines can be developed to feed from Epic's Clarity database. UF IDR is rolling out data in the OMOP CDM, which can potentially services APIs (e.g., through OMOP on FHIR); however, customized builds will be required.

Q8. If you export data from your data repository, what file format(s) of the exportable data is available?

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A8. OMOP (see A7)

Q9. What is your enterprise interface engine?

A9. MIRTH is our interface engine and it is HL7

Q10. What type of security or risk assessment/review is necessary?

A10. UF IT and UF Health IT collaboratively conduct comprehensive risk assessments for each project. Their approval is required.

Q11. Is your OnCore your "source of truth" for all clinical trials (and all in/out of cancer)? What key information resides discreetly? What other important data might benefit from NLP or other auto-extract and structuring capabilities?

A11. OnCore does serve as our "source of truth" for the interventional human subjects trial portfolio across the cancer enterprise. Key data includes information housed within the eligibility tab (not fully utilized at present). This would be most relevant to extract for subject screening purposes. Currently, most elements within PC Console's main tab are populated for the oncology clinical trial portfolio.

Q12. Besides Epic and OnCore, are there are clinical research apps/modules you rely heavily on or need to interface to? Do you anticipate this changing? If so, please share any pertinent information. What are these systems? Any upgrades or version changes expected during your ideal CTM implementation window?

A12. Not at present however the University is exploring e-regulatory software

Q13. Where do your protocols reside, and in what format (i.e., IRB, CTMS, EREG)?

A13. Protocols reside in OnCore under the documents tab. Most are uploaded in a native PDF format.

Q14. Do you have a current-state workflow analysis documentation available to share?

A14. No documentation available

Q15. Do you utilize any program, such as: CancerLinq or Blue Button? What reliance on them is part of current and/or future ideal state integration + workflow?

A15. No

Q16. What percentage of your patients are offered a clinical study/trial?

A16. These metrics are not currently available

Q17. Do you rely on the cancer registry for any supplemental trial information or study design/feasibility? What is that process and have you identified any automation opportunities?

A17. UF Health tumor registry data is integrated into the IDR and OMOP.

Q18. Are you evaluating other decisions (procurement or otherwise) on the cancer center or health system level that might change any scope of this RFP?

A18. No

Q19. For "Business requirement 4". Ability to interface with UF clinical & research systems and enterprise data warehouse - Is this a RAVE EDC interface? What is the technical interface to their data warehouse?

A19. See answers to A7.

Q20. For "Business requirement 12". Ability to reference with reference laboratories outside UF via API - Can technical details of these interfaces be provided? Which reference laboratories?

A20. The Hospital Lab uses ARUP as their main reference lab and UF Pathology Lab uses LabCorp as their main reference lab. We would have to work with the interface team to understand how those interfaces are defined.

There are other reference labs the hospital use that we do not have interfaces with at present.

Q21. For "Business requirement 13". Ability to interface with the institution's Clinical Trials Management System (CTMS), OnCore.- What data and exchanges are in scope?

A21. Preferably screening data (e.g., who's eligible through e-screening) should flow into OnCore to connect to support recruitment workflow. Flowing these data into the data warehouse (IDR) will also be desired (not required).

Q22. For "Reporting requirement 5". Ability to view KPI's - Can UF provide detailed KPI requirements?

A22. We do not have detailed KPI requirements however we are interested in reporting on key operational measures such as the rates at which screened patients are converted into accruals, reasons for screen failures, and so on.

Q23. For "Reporting requirement 6". Ability to report at patient, trial, provider, clinic, department, enterprise and diagnostic code cohort levels - How does UF assign departments, enterprises and diagnostic codes to cohorts?

A23. Department can be defined at the provider or management group level depending on the query. Enterprise is defined at the protocol library level and diagnostic codes are assigned based on disease site and histology assignments at the subject level.

Q24. How important is the need to recruit across the research enterprise vs the oncology space?

A24. Oncology space is first priority; however, UF Health prefers to have an enterprise solution. We need to make sure the solution deployed in the oncology space can be applicable (with minor changes) to support other areas.

Q25. Is there an update and when will we be notified if we should provide a presentation?

A25. The proposals received by UF will be reviewed by the committee and any follow up information will be communicated by UF Procurement.