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May 2nd, 2022

ADDENDUM #2 to the University of Florida ITN22NH-132 E-Regulatory and E-Consent Software for Clinical Research to be opened on **May 18th, 2022 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 **ITN22NH-132** 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:

1. **Responses to technical questions and inquires submitted prior to 5:00pm, April 15th, 2022.**

Sincerely,

Nicola Heredia

Nicola Heredia, Director
Procurement Services

Please acknowledge receipt of Addendum #2 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

ITN22NH-132 E-Regulatory and E-Consent Software for Clinical Research

1. **With respect to eRegulatory Application Functionality Section, is there a requirement that the document templates stored in the application be editable within the application as well?**

A. There is no requirement that documents be editable within the application.

2. **Is there a requirement for electronic Training Log functionality in addition to Delegation of Authority logs?**

A. Yes.

3. **With respect to eConsent Application Functionality Section, can you give some guidance or context as to what expectations of the UF IRB need to be met?**

A. OHRP has guidance on this that must be followed: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html#toc1

Additionally, any system must be FDA part 11 compliant.

This is our Investigator guideline on E-Consent: https://irb.ufl.edu/wp-content/uploads/Electronic-Informed-Consent.pdf

An insight from the practice of reviewing eConsents tells us the following about the key features of a system that is conducive to compliance: establishing version control for the consent is crucial, document retention (making sure that study team downloads a consent so it's not deleted from the cloud) and having a way of sharing a copy of the signed consent with a study subject are a must.

4. **Are the Requirements sections of the ITN meant to be open topics for vendors to speak to or do you have a more defined set of questions for each category? Generally, there is a functional and non-functional questionnaire to accompany the RFP process.**

A. Open topics for vendors. ITN may create more discussion around functional & non-functional requirements

5. **How many active cancer trials does UF currently have? How many of these will need to be migrated over to the new eReg solution?**

A. 260 active studies, approx. 90 will need to be migrated. This does however depend on the platform capabilities

6. **What % of cancer trials are industry sponsored vs. investigator initiated?**

A. Network (NCTN, BMT-CTN, etc.) 53%
B. Industry 38%
C. IIT 9%

7. **How many active non-cancer trials does UF currently have?**

   A. 590

8. **What % of non-cancer trials are industry sponsored vs. investigator initiated?**

   A. Industry 49%
   B. Investigator initiated (grant-funded and internally funded) 51%

9. **How many new cancer trials, i.e., new study starts, does UF plan to initiate in Year 1, Year 2, and Year 3? Please break out numbers by industry sponsored and investigator initiated.**

A. *The approximate number of studies that we initiate each year, based on the prior 3 years:*

27 studies per year
13 Network
11 Industry
5 IIT

10. **How many new non-cancer trials, i.e., new study starts, does UF plan to initiate in Year 1, Year 2, and Year 3? Please break out numbers by industry sponsored and investigator initiated.**

A. 255 studies per year
   a. 126 industry funded studies
   b. 129 investigator-initiated studies

11. **What is the annual number of new studies started and approximate newly enrolled patients per year?**

A. Approximately 300 new studies per year including oncology and non-oncology; approximately 2,000 patients enrolled per year including oncology and non-oncology

12. **What is the annual number of ongoing studies and approximate number of annual reconsents for existing clinical trial patients?**

A. Annual number of ongoing studies is around 1,300 for a one-year period or 1,100 on any given day. This includes oncology and non-oncology. The number of reconsents annually is unknown.

13. **What depth of eSource capability does UF need to support current studies?**

A. Currently eSource for majority of study teams is maintained as a shadow source file for each participant, and that would include document extraction from EHR or other non-clinical labs,

imaging, etc. Indexable electronic solution to replace shadow cart and permits remote monitoring functionality for electronic redaction of documents for external sharing/remote monitors.

14. Are you planning to store patient clinical data within the eReg solution for Remote Source Data Verification (RSDV)?

A. No, we are not, we would expect an eSource to be the platform for this.

15. What is your number of locations?

A. UF Health Gainesville Outpatient Clinics/Complex as a singular location and 4 distinct Inpatient facilities/hospitals (Gainesville, Jacksonville, Leesburg, The Villages)

16. What is the number of staff to be trained? What is the approximate number of expected new staff to be trained annually thereafter? Would the training be on-site or remote initial training?

A. Training usually done virtually through an eLearning platform and is tracked in a system that is integrated with PeopleSoft

17. What are the patient languages to be supported for eConsent?

A. American English, Spanish (dialect to be determined)

18. Will you need Single Sign-On Support?

A. Yes, required.

19. Will there be a CTMS integration? If yes, which CTMS?

A. Yes, OnCore

20. How many eConsent education video creations are needed, in what languages?

A. This information has not yet been decided

21. Are there specific unique feature requests for UF for either eReg, eSource or eConsent?

A. The University of Florida & Office of Clinical Research desires an out of the box solution with standardized feature sets. We normally do not pursue site-specific customizations due to increases in cost.

22. How many New Industry Sponsored Studies do you start each year (365-day period)?

A. Approximately 150 new industry-sponsored studies per year including oncology and non-oncology

23. How many New Investigator Initiated Trials do you start each year?

A. Approximately 60 internally funded, investigator-initiated trials per year including oncology and non-oncology

24. How many Grant or Government Funded Studies do you start each year?

A. Approximately 115 grant-funded studies each year including oncology and non-oncology

25. How many multisite trials does UF manage?

A. UF participates in approximately 550 multi-site trials per year, approximately 20 of these are study where the main PI is a UF faculty that is managing the sub-sites.

26. Will you be looking to migrate documents from existing studies into the new system that exist in electronic format current state? If so, how many?

A. Each of our study teams will make specific decisions as to protocol migration. Yet Undetermined.

27. Is your OnCore hosted on-premises or in cloud?

A. Cloud

28. How many separate instances of OnCore are present at UF AND need to be integrated with the new system?

A. One

29. Do you use "Management Groups" inside of OnCore to separate departments?

A. Yes. Mgmt groups are used and part of our security model for protocol access.

30. How many New Industry Sponsored Studies do you start and plan to use eConsent for each year (365-day period)?

A. Approximately 150 new studies per year, including oncology and non-oncology

31. How many New Investigator Initiated Trials do you start and plan to use eConsent each year?

A. All new FDA regulated studies; we start approximately 60 new internally funded, investigator-initiated studies per year including oncology and non-oncology

32. How many Grant or Government Funded Studies do you start and plan to use eConsent each year?

A. Approximately 115 new studies per year

33. What is the total number of participants you plan to consent via the eConsent tool per year? 0-5000, 5001 – 10000, 10000+?

A. 0-5000

34. Could you share more with us about what you are looking to accomplish around patient recruitment? We currently have no functionality around recruitment with the exception of consenting participants.

A. Ability to data mine the number of consents, reconsents for trials

35. Are looking for assistance with finding participants who meet criteria?

A. Interested but not required

36. Is UF's expectation that both eReg and eConsent platforms are fully operational by October 1?

A. Yes

37. When does UF plan to award a supplier?

A. End of Q2 2022

38. Is there any flexibility around the implementation timeline?

A. There is some degree of flexibility that can be discussed during the negotiation phase.

39. Can UF accept responses to this ITN through email?

A. Currently, UF does not accept responses through email. All hard copies must be received as detailed in the ITN document.