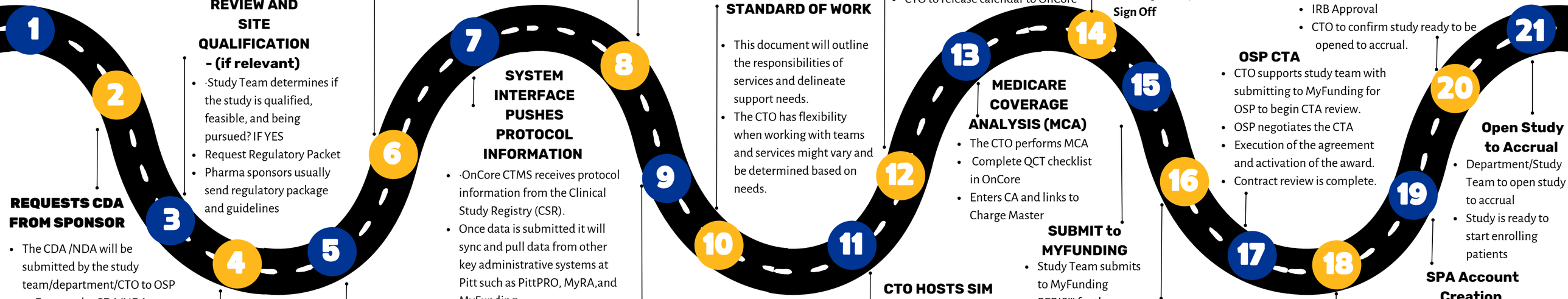
START-UP, REVIEWS & PRE-AWARD CTMS WORKFLOW



1 SPONSOR REACHES OUT WITH INTEREST OR INVESTIGATOR INITIATES STUDY

- Sponsor shares protocol synopsis
- Sites might be asked to complete feasibility questionnaire
- PI/Institution states interest in and decide to move forward

2 REQUESTS CDA FROM SPONSOR

- The CDA /NDA will be submitted by the study team/department/CTO to OSP to Execute the CDA/NDA
- If the sponsor has a Master CDA/NDA with Pitt proceed to step 3.

3 SPONSOR REVIEW AND SITE QUALIFICATION - (if relevant)

- ·Study Team determines if the study is qualified, feasible, and being pursued? IF YES
- Request Regulatory Packet
- Pharma sponsors usually send regulatory package and guidelines

4 INITIAL SUBMISSION IRB

- Study Team will begin application to the IRB and get the Study ID to use on the Clinical Study Registry submission.

5 SUBMIT TO CLINICAL STUDY REGISTRY (CSR)

- Study Teams/Department will submit study information to the “Clinical Study Registry” once study has been deemed a clinical trial per the NIH Clinical Trial Definition.
- Study Team/Department team members can begin OnCore Prerequisite Training

6 FINALIZE REGULATORY SUBMISSION

- Study Team to compile regulatory documents
- Study Team submits protocol to IRB and IRB Record is created in PittPRO, or another IRB record might be created (if an external IRB is used).
- PittPRO IRB is integrated with OnCore CTMS
- A link for PittPRO is available in Oncore to facilitate access.

7 SYSTEM INTERFACE PUSHES PROTOCOL INFORMATION

- ·OnCore CTMS receives protocol information from the Clinical Study Registry (CSR).
- Once data is submitted it will sync and pull data from other key administrative systems at Pitt such as PittPRO, MyRA,and MyFunding

8 IRB REVIEW PROCESS AND STATUS UPDATE

- ·PittPRO is integrated with OnCore CTMS for direct access to files and statuses.
- If using external IRBs,the Study Team/Department will need to record the IRB decision in OnCore manually.

9 STUDY INITIATION MEETING PREPARATION

- Study Teams/Department will send required documents to the CTO SIM Team.

10 CTO PREPARES STANDARD OF WORK

- This document will outline the responsibilities of services and delineate support needs.
- The CTO has flexibility when working with teams and services might vary and be determined based on needs.

11 CTO HOSTS SIM

- The CTO meets with the Study Team/Department to learn more about the study and review the documentation.
- CTO provides SOW to team.
- CTO reviews Minimum Footprint in OnCore CTMS
- PI, Primary Coordinator and Research Manager have completed training.

12 CALENDAR BUILD

- CTO builds calendar based on protocol.
- Department/Study Team Reviews Calendar
- CTO makes requested updates.
- **Department/Study Team approves calendar with sign off**
- CTO to release calendar to OnCore

13 MEDICARE COVERAGE ANALYSIS (MCA)

- The CTO performs MCA
- Complete QCT checklist in OnCore
- Enters CA and links to Charge Master

14 MCA REVIEW & APPROVAL

- Department/Study Team to Review final determination
- The CTO processes MCA reconciliation if needed
- MCA Fiscal Review by UPMC/Revenue Cycle
- **PI to review, and approve Coverage Analysis in OnCore - Sign Off**

15 SUBMIT to MYFUNDING

- Study Team submits to MyFunding PERIS™ for the School Review process by Research Administration Office

16 BUDGET BUILD

- CTO to set up budget template in OnCore CTMS
- CTO to export budget for Department/Study Team to begin budget negotiations.
- Budget is finalized and CTO begins reconciliation
- CTO to release budget in OnCore

17 OSP CTA

- CTO supports study team with submitting to MyFunding for OSP to begin CTA review.
- OSP negotiates the CTA
- Execution of the agreement and activation of the award.
- Contract review is complete.

18 IRB APPROVAL

- Department/Study Team submits IRB Approval in OnCore if using an external IRB.
- If using PittPRO the record will be created via system integration.

19 PREACTIVATION

- Department/Study Team to complete SIV
- **Protocol Sign Offs - Primary Coordinator, Department Manager or PI**
- CTO confirms account is created by Sponsored Projects Accounting (SPA)
- CTO confirms Contract is fully executed
- Letter from Sponsor
- IRB Approval
- CTO to confirm study ready to be opened to accrual.

20 SPA Account Creation

- SPA sets up account in financial system

21 Open Study to Accrual

- Department/Study Team to open study to accrual
- Study is ready to start enrolling patients

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APPROVED BY: P.CORBY 21NOV2024
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