Clinical Trial Conduct at UOC

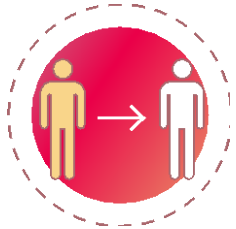
Pre site selection visit

Presentation

1. **General Overview** of study start up procedures
2. Clinical Trial **Facilities**
3. Clinical Trial **Management System** (CTMS)
4. **Websites**
5. UOC **Community Engagement**

General Overview of study start up procedures

General Overview



PI Contact

- Sponsor contacts concierge service specialist or potential Investigator at UCalgary regarding interest of new trial

CDA

- CDA is executed via Legal Department
- UCalgary Investigator receives protocol

PSSV

- Feasibility questionnaire completed if necessary
- Schedule Pre Site Selection Visit if necessary
- Site selection confirmed

Study Start Up Procedures

CTA Uploaded to SharePoint

- CTA, protocol and budget uploaded to SP by study coordinator
- CTA is reviewed by CSM Legal and budget review is conducted by the CCCR
- Both reviews are being done in parallel

CTA/Budget Negotiations with Sponsor

- CSM Legal completes initial review of the CTA and sends to the sponsor for review
- The CCCR will work with the PI/coordinator to build the final budget
- Once the budget has been finalized, the CCCR will conduct a final review before they send it to the sponsor for review
- Negotiations can take anywhere between 6-8 weeks, or longer depending on the complexity of the CTA or budget

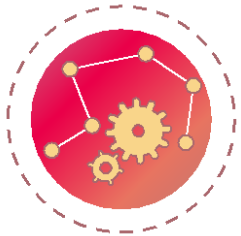
Ethics, Budget, Contract and Final Set-up

- If the UOC site is selected, ethics work commences
- UOC has local REB (CHREB - Conjoint Health Research Ethics Board)
- Ethics submission can be made at the same time as the submission of the CTA
- The contract, budget and ethics submission can all be made at the same time. All three will be reviewed simultaneously

Clinical Trial Start-up

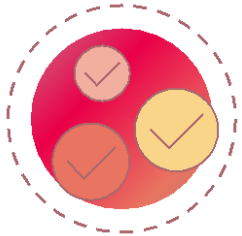
Submissions

- REB submission
- Contract submission
- Budget submission
- AHS resource request
- Service Requests



Processing

- REB review
- Contract negotiations
- Budget negotiations
- AHS review
- Service reviews



Approvals

- REB approval
- Budget approval
- Contract execution
- AHS approvals
- Service approvals

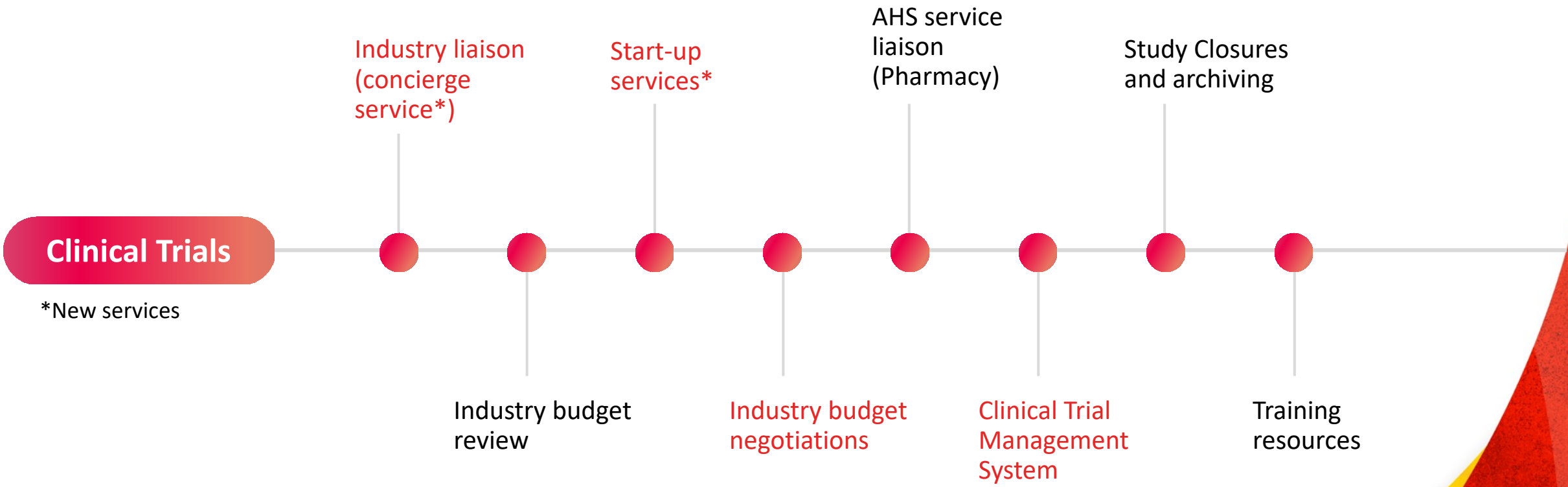
Transition

- W21C Coordinator Pool
- Departmental Coordinator

Calgary Centre for Clinical Research - CCCR

- Clinical Research Administration Support at the Faculty Level
- Support for All Disease Areas
- Major areas : GI, Cardiac, Neurology, Pediatrics, Respiratory, Nephrology, Psychiatry, Oncology

Services CCCR Provides



*New services

Quality Assurance Program

This program provides support to the University of Calgary clinical research community to help foster and maintain our reputation as a world-class center for clinical research.

1. **Conducting internal** regulatory file **reviews**

2. **Guiding researchers** through the regulations and guidelines governing research project (e.g. University policies, REB SOPs, TCPS2, ICH-GCP, Health Canada, US FDA regulations, etc.)

3. **Supporting researchers,** who are undergoing inspections from regulatory bodies, such as Health Canada and the FDA

4. **Implementing and maintaining N2 Standard Operating Procedures** for clinical trials conducted at the University of Calgary

Enhancing Clinical Trial Training

SPOR Pragmatic Clinical Trial Certificate

- 5 Months Training for clinical trial staff and investigators
- Biannual course; 129 learners trained to date
- http://sporpctcertificate.ca/

Mandatory Clinical Trial Certification

- CITI certification program introduced in fall 2018.
- Since them, increase in the number of certification in research staff GCP from 510 to 1381 and HC Division 5 from 234 to 747.

Clinical trials quality assurance program

- 6 to 8 file reviews/a; feedback and education for PI and team
- Resource for all regulatory matters
- https://research.ucalgary.ca/conduct-research/ethics-compliance/quality-assurance-clinical-trials

Medical Records

CURRENTLY

- Both electronic and paper medical records
- EMR system : ARIA/ Sunrise Clinical Manager/Netcare
- CRA's have no direct access to EMRs
- However, over the shoulder access can be granted and UOC have memo in place with explanation
- Research staff have experience utilizing Electronic Data Capture systems such as InForm, Redcape, Rave

IN PROCESS IMPLEMENTATION

- One EMR(EPIC)
- Direct EMR access for monitors

SSV-Frequently Asked Questions

Q **Does your site utilize a local or central IRB?**

A Local IRB–University of Calgary Conjoint Health Research Ethics Board

Q **What documents are required for submission to your IRB?**

A Protocol, ICF, IB and all patient facing documents

Q **Do clinical trials require approval by a separate review committee at your site?**

A Yes, only if using AHS Resources to conduct clinical trials

Q **Does this review happen in parallel with IRB review?**

A No, follows REB approval

Q **If your site uses a local IRB, what are your submission timelines?**

A There are no concrete submission deadlines for our REB. The CHREB meets each month on 1 st and 3 rd Thursday of each month.

Q **Do contract/budget negotiations run in parallel and can negotiations occur concurrently with IRB submission/review?**

A Yes, target timeline for start up is 8 weeks from the receipt of the regulatory package to all approvals

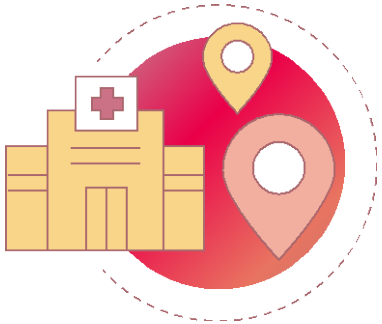
Q **How many weeks does this review take, on average?**

A 2-4 weeks after REB approval

Q **Please specify the name of any committee(s) required to approve new sponsored clinical research**

A If applicable - Alberta Health Services Administrative Approval

Clinical Trial Facilities



- Heritage Medical Research Clinic
- Research pharmacy services
- Diagnostic imaging
- Laboratory services
- Alberta Health Services
- Record storage Services

Clinical Trial Facilities

Heritage Medical Research Clinic

Foothills Hospital Campus
TRW Building, 5th Floor

- This unique agency merges patient care and clinical trials
- Services provided include: a fully equipped laboratory, electrocardiograms, patient reception, consultation rooms, examination rooms, as well as an area for monitoring visits and storage of study specific equipment. The clinic is owned and managed by the University of Calgary
- Phase 1 overnight facility with 2 designated ICU beds for clinical research
- Specialized clinic room to support pediatric trials and special need patients

Clinical Trial Facilities

Heritage Medical Research Clinic

ICU Bed

Clinical Trial Facilities

Research Pharmacy Services

- Currently University of Calgary Researchers utilizes AHS research pharmacy at different hospitals and health care facilities located in Calgary. AHS research pharmacy has GCP trained pharmacists with experience in storing, preparing and managing study drug accountability
- Refrigerators and freezers are centrally alarmed
- **A -80 non-cycling freezer is available for drug storage if required**
- Pharmacy will not use trial specific temperature logs or recording devices. All temperatures are recorded daily (excluding weekends and statutory holidays) on a site specific temperature log, using the temperature recording devices we have onsite (i.e. the digital thermometers located in each of our refrigerators and freezers). Copies of temperature logs will be filed in trial specific pharmacy binder
- Biosafety cabinet for containment level 2 trials

Clinical Trial Facilities

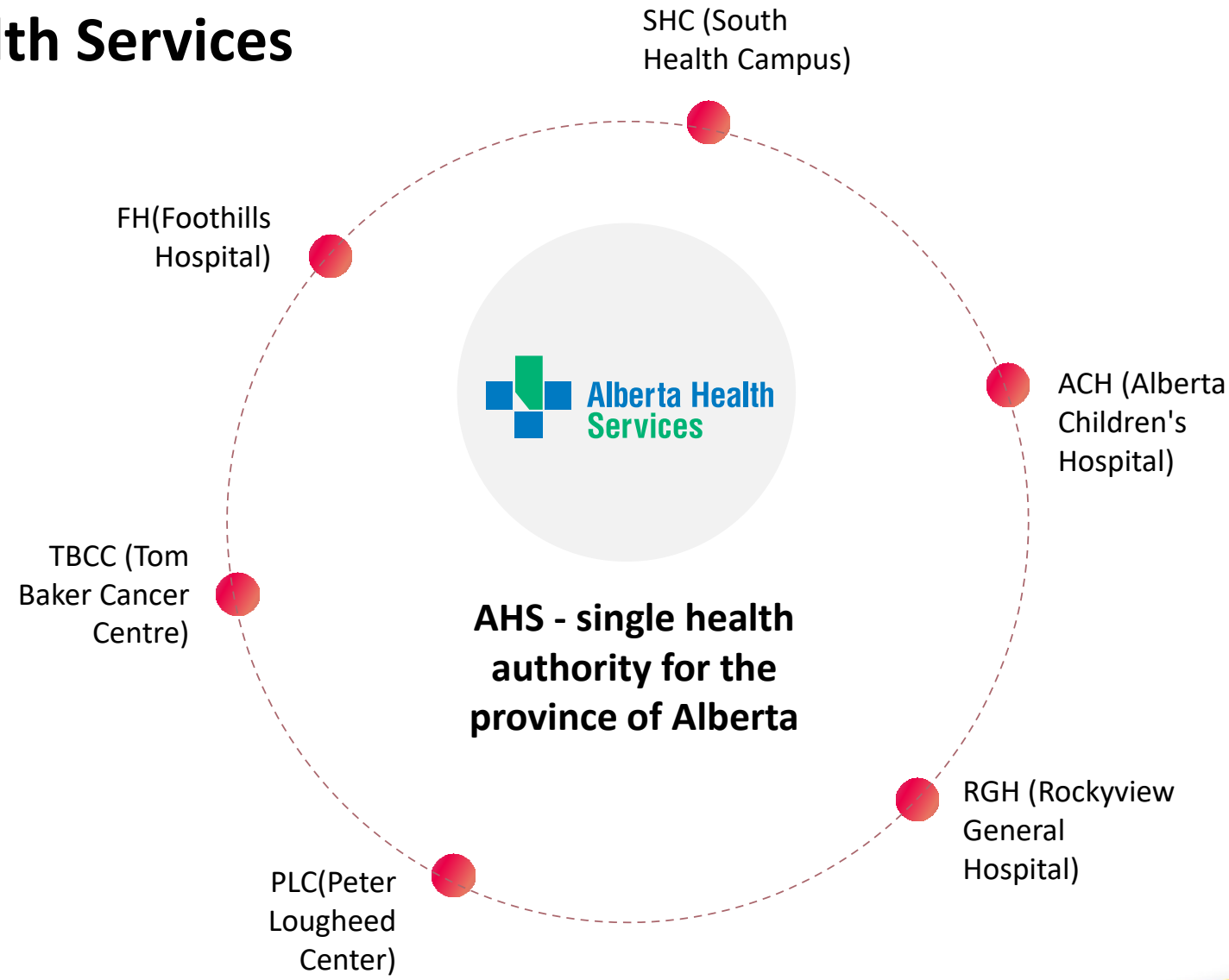
Diagnostic Imaging and Laboratory Services

University of Calgary Researchers have access to:

- Advance imaging services such as MRI, CT, MRE, PET
- Alberta Precision Laboratory services **which include Anatomical Pathology**

Clinical Trial Facilities

Alberta Health Services



Long-term Storage Facilities

Study records are sent to storage facility called the High Density Library (HDL), located at the Spy Hill campus, University of Calgary.

High Density Library
Spy Hill Campus
11711, 85 Street NW
Calgary, AB T3R 1J3

Clinical Trial Facilities

The Centre for Mobility and Joint Health (MoJo facility)

- This is a state of the art imaging facility with a research focus Refrigerators and freezers are centrally alarmed.
- Images are acquired by registered Medical Radiation Technologists and staff have been trained in GCP standards.
- Modalities accessible include: EOS, CT, X-ray, DXA, Ultrasound, extremity MRI, HR-pQCT and pQCT.
- The MoJo team works with sponsors to create protocols that suit the needs of the study.

SSV-Frequently Asked Questions

Q **Does your site have access to a freezer (-80 C), refrigerated centrifuge, and dry ice?**

A Yes, HMRC has all these facilities for clinical trials use

Q **Does your site have access to overnight beds for research purpose?**

A Yes, University of Calgary has 2 beds specifically allocated for clinical research to facilitates overnight stay as well can provide ICU level care when needed

Q **Does your site have experience receiving IP in liquid Nitrogen?**

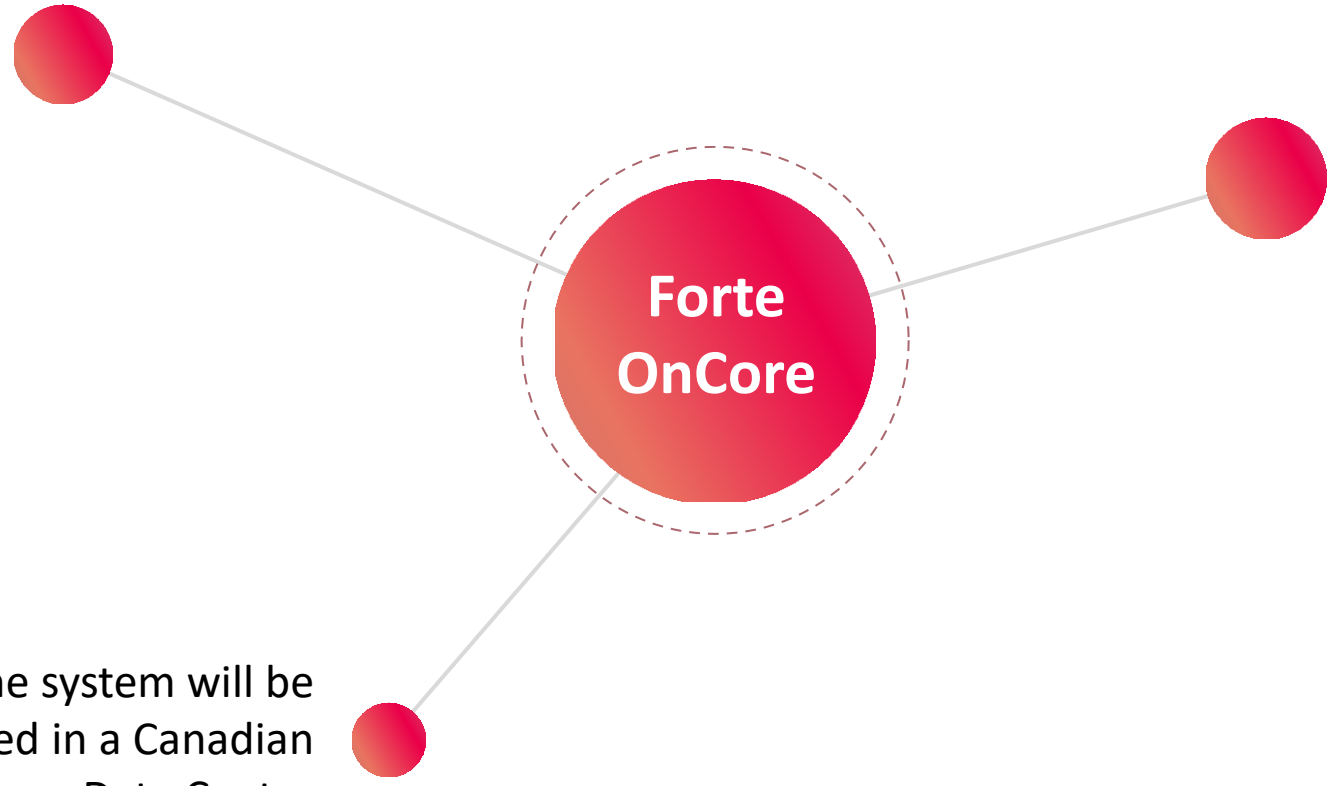
A Yes, HMRC has experience receiving IP in liquid N2

UNIVERSITY OF CALGARY

Provincial Clinical Trial Management System Initiative

Forte OnCore - Overview

The Forte system is a Cloud solution



The system license will be held by the U of C Participating partners will sub-license with the UC

The system will be hosted in a Canadian Data Centre

OnCore – Core Capabilities

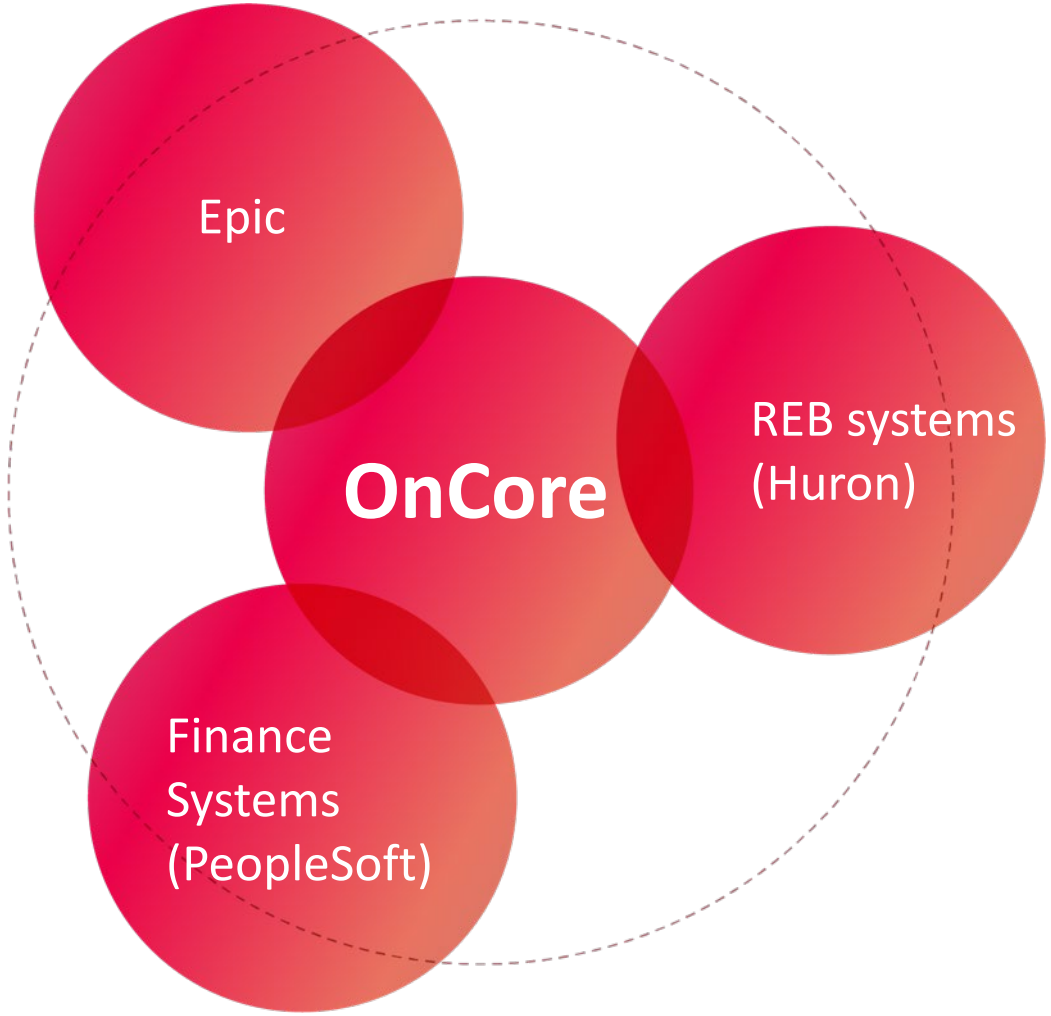
Centralized study calendar

Financial management

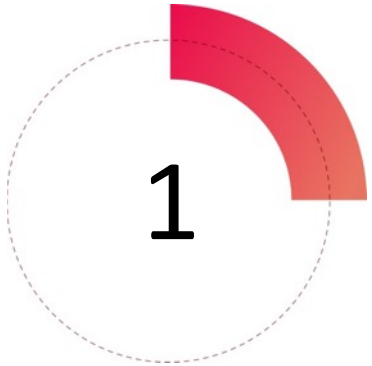
Budgeting/ Invoicing

Turnkey reporting

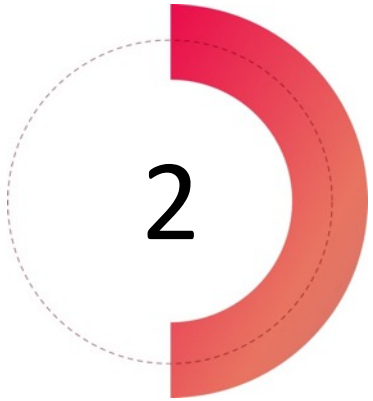
OnCore – Integration



Goals



Improve patient safety



Expand CT activity

Enhance CT performance

Enhance CT reporting

Websites

Attract Clinical Trial Investment

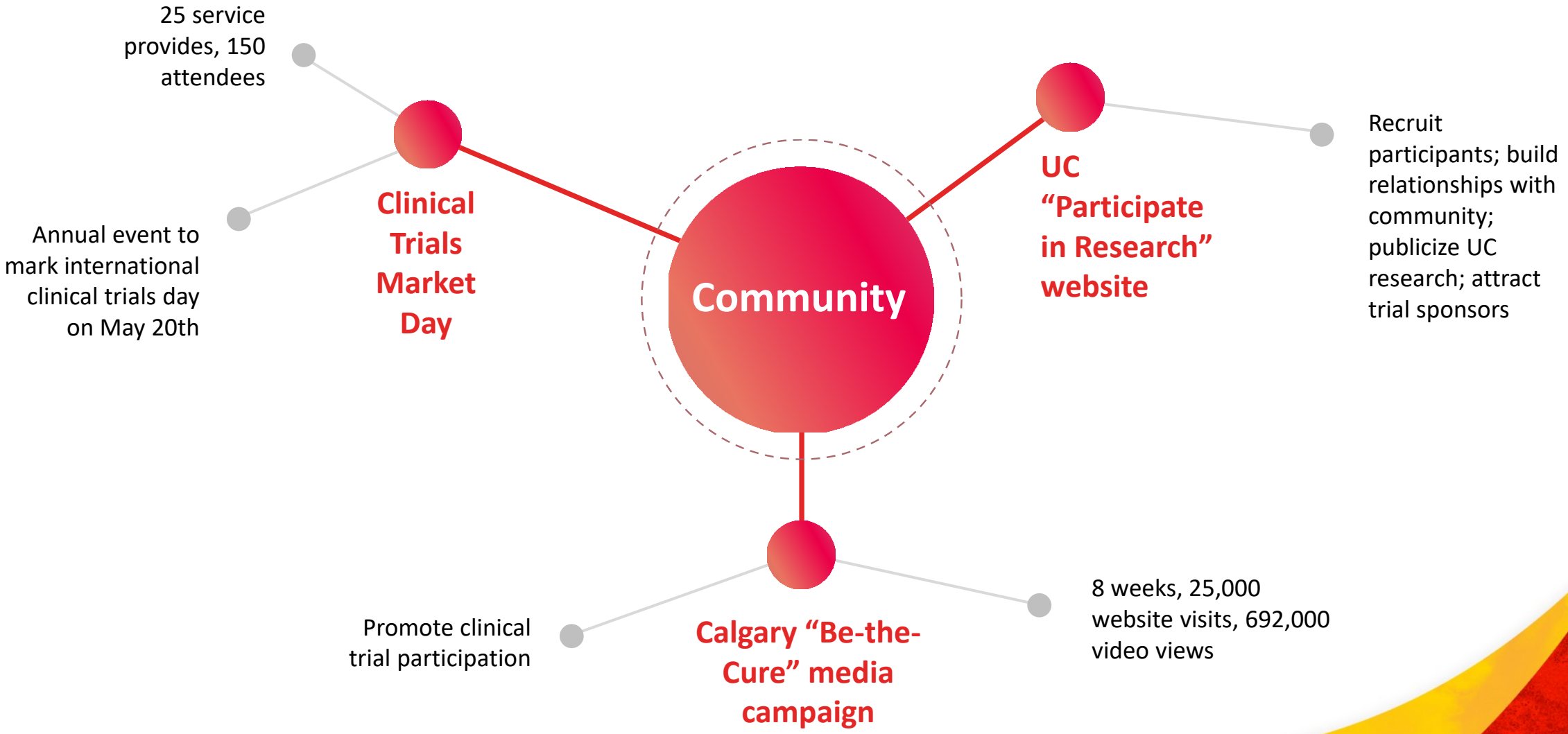
Updated Websites:

Heritage Medical Research Clinic
Calgary Center for Clinical Research
Centre for Mobility and Joint Health
Ward of the 21st Century(W21C)
Integrated Management Platform to Accelerate Clinical Trials

New Websites:

Clinical Trials @ U of C

Fostering Community Engagement



Thank you!

Questions?

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