Please note that these slides were created during the earlier development phase.

Details are subject to change and should not be applied without confirmation.

PCORnet ADAPTABLE Data Strategy Discussion

Friday, September 25, 2015

Hosted by Lesley Curtis, PhD and Schuyler Jones, MD

Facilitated by Shelley Rusincovitch

Adaptable

The Aspirin Study

pcornet

Welcome & Overview

Prior discussion: Phenotyping

- Working session held on September 4, 2015
- Slides, recording, and summary available on Central Desktop: https://pcornet.centraldesktop.com/p/ZgAAAAAAZgS3

Setting the stage for today's meeting

Our scope for today:

- Discuss the current status of development for the ADAPTABLE data components
- Outline considerations and areas needing further assessment

Setting the stage for today's meeting (2)

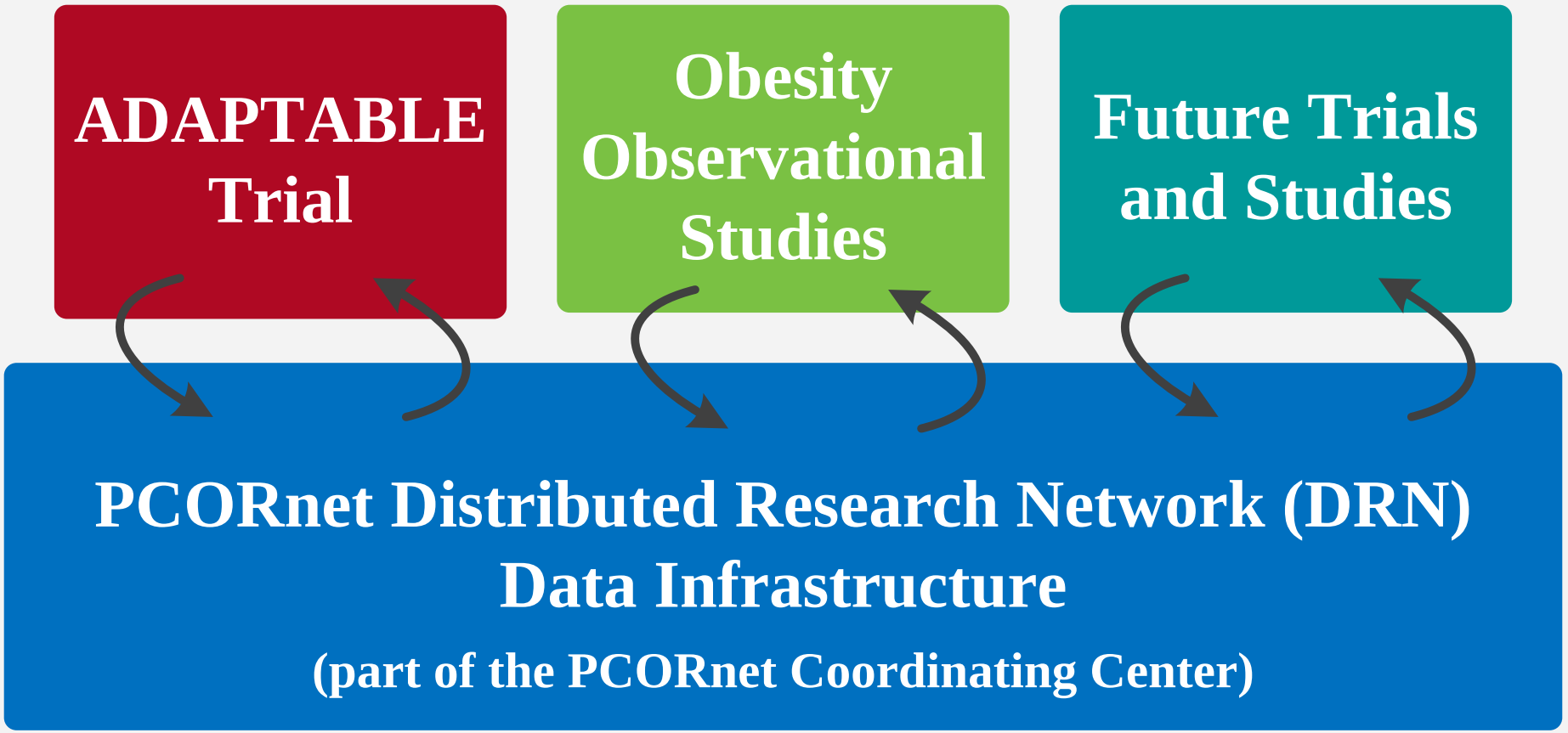
Important context:

- The trial protocol is not yet formally finalized
- Contracting is not yet executed
- Given this state, today's conversation is not intended to assign tasks or effort for networks; however, networks may choose to "work ahead" if they feel appropriate

Final caveat

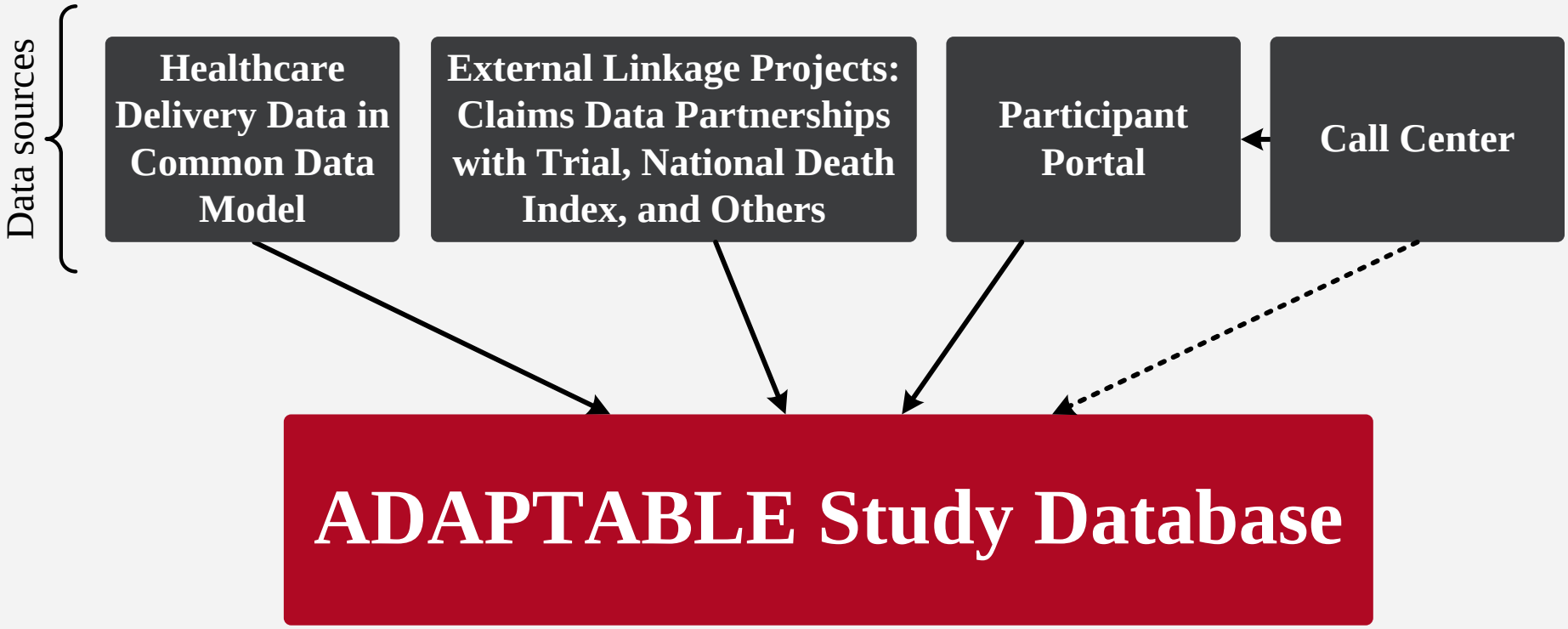
- We'll be talking today about the *current* state of development planning
- These details may change during the iterative design, development, and implementation of the project

High-level Overview

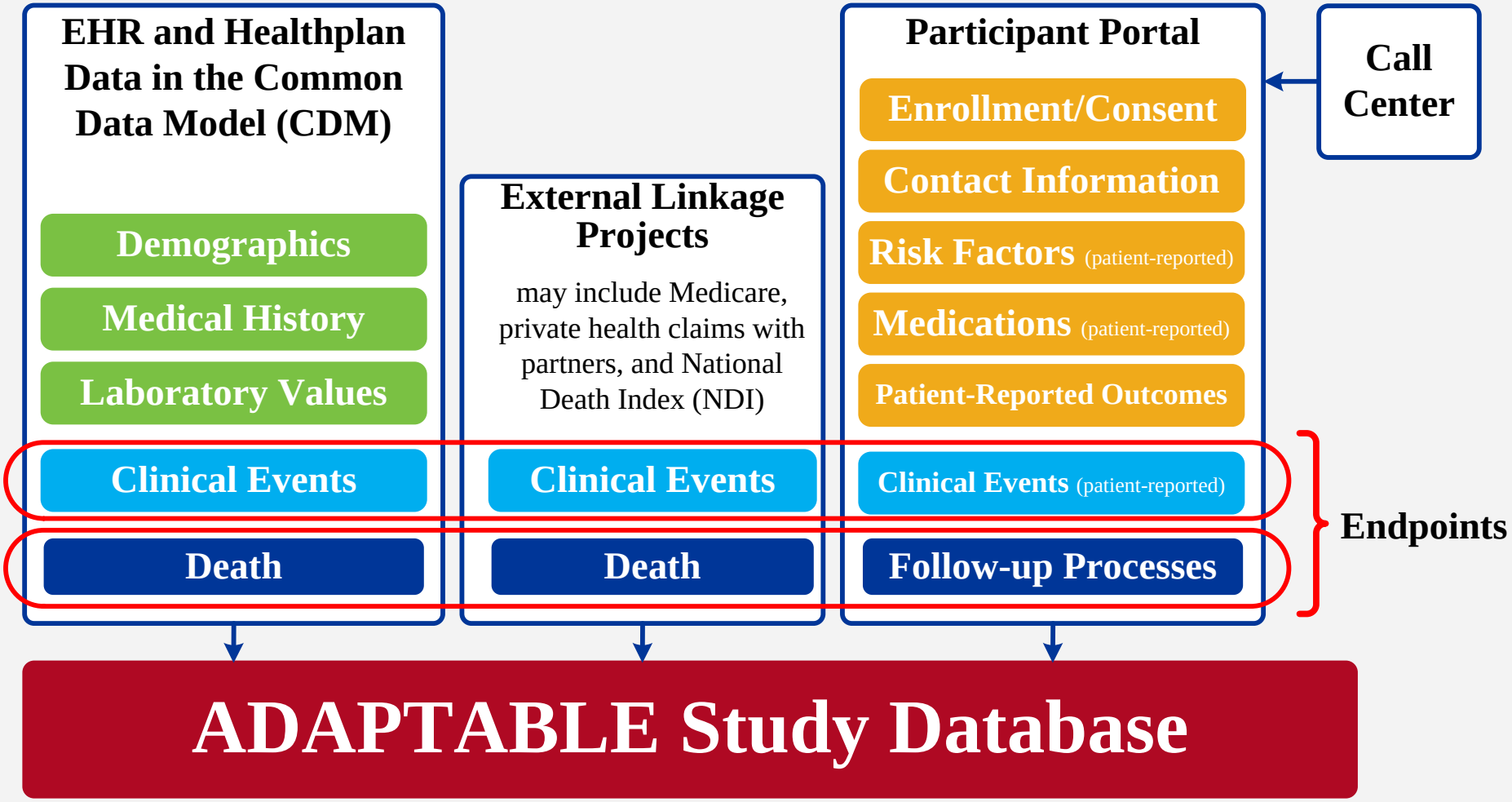


The ADAPTABLE trial is based upon the foundation of the PCORnet DRN data infrastructure. PCORnet trials and studies form a continuous cycle of improvement in data infrastructure development.

Modules of the data landscape amalgamate into the study database



How it all comes together for analysis (draft version)

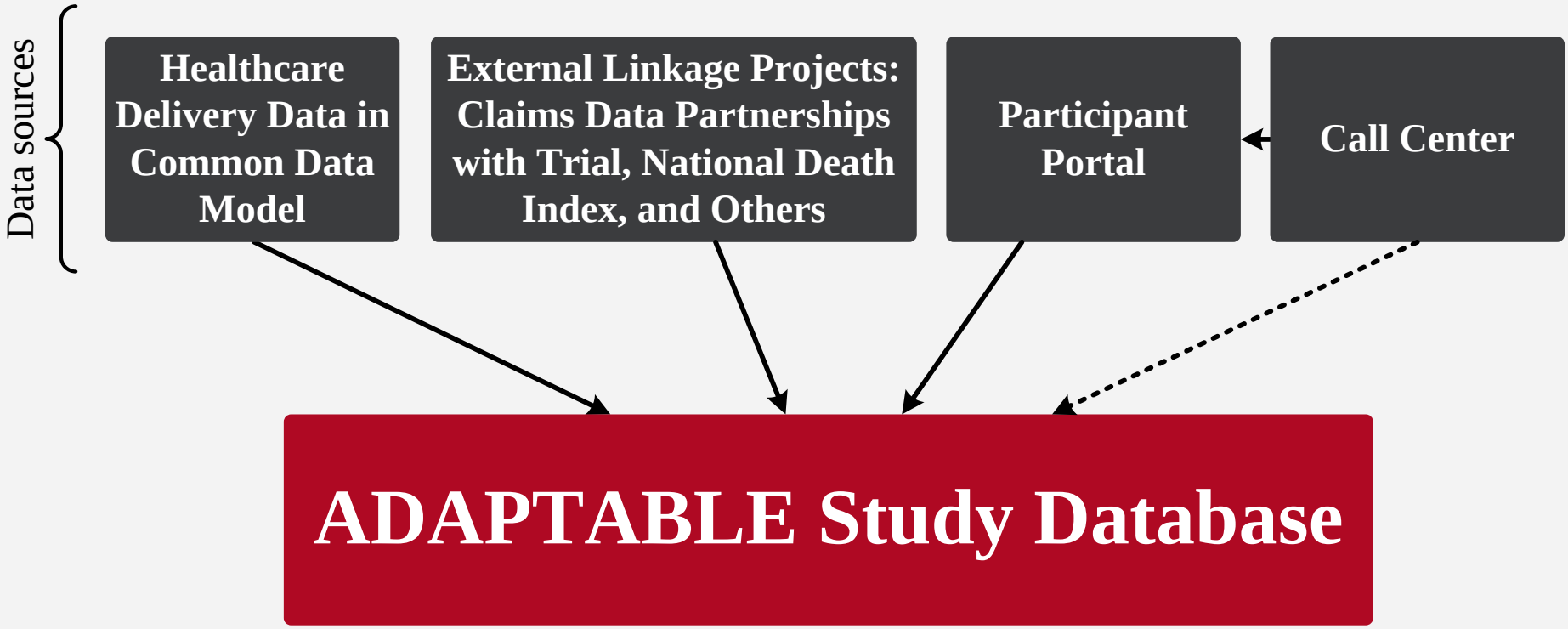


Adaptable

Please note: The CRF is not yet finalized.

Screening and Recruitment

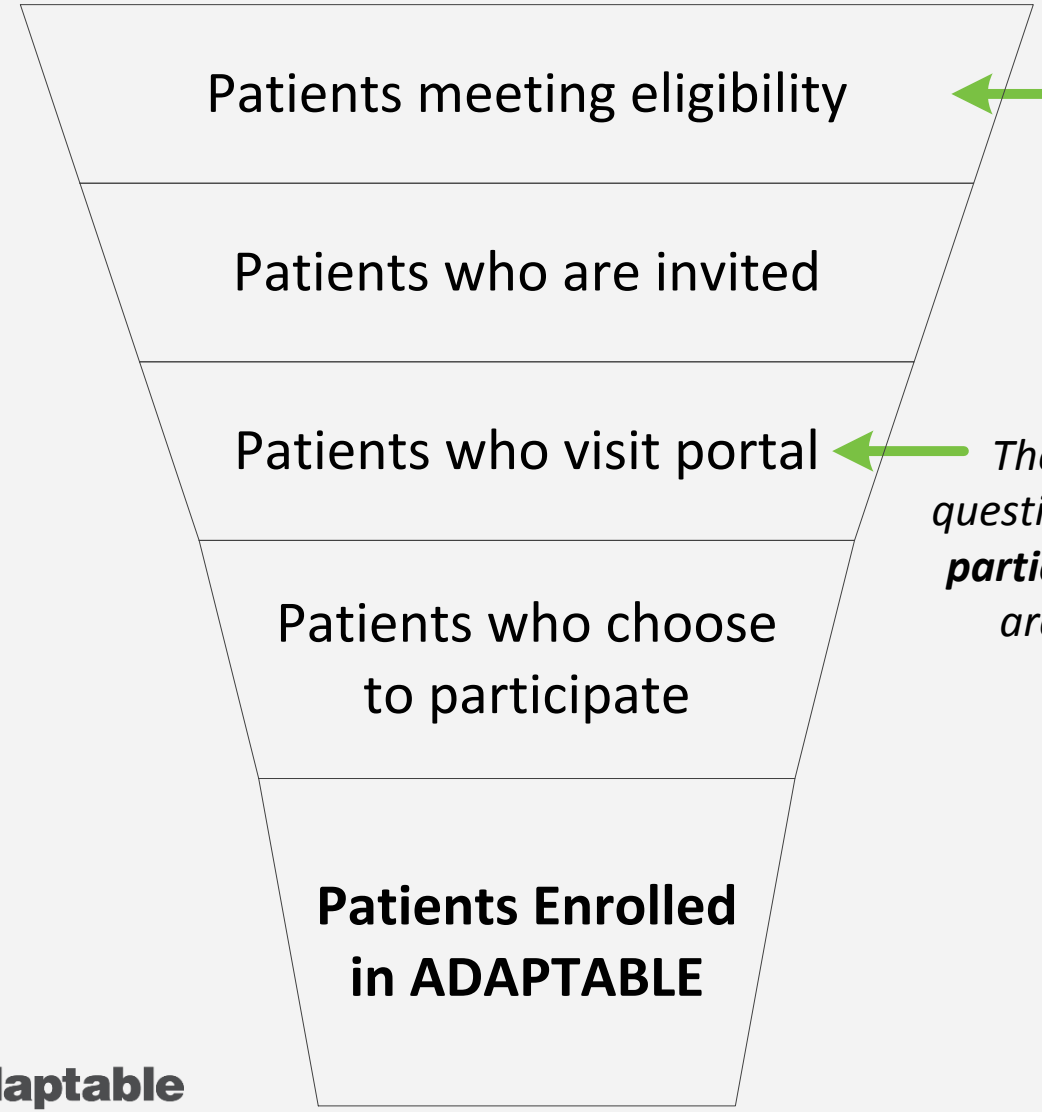
What's not on this diagram? Screening and recruitment



Screening and recruitment development

- Sites and/or networks are heterogeneous, and expected to have different processes for identifying, contacting, and inviting potential trial participants
  - “Base phenotype” (to be developed by ADAPTABLE CC) will be modifiable by individual sites to best suit their processes

Potential Participant Pool

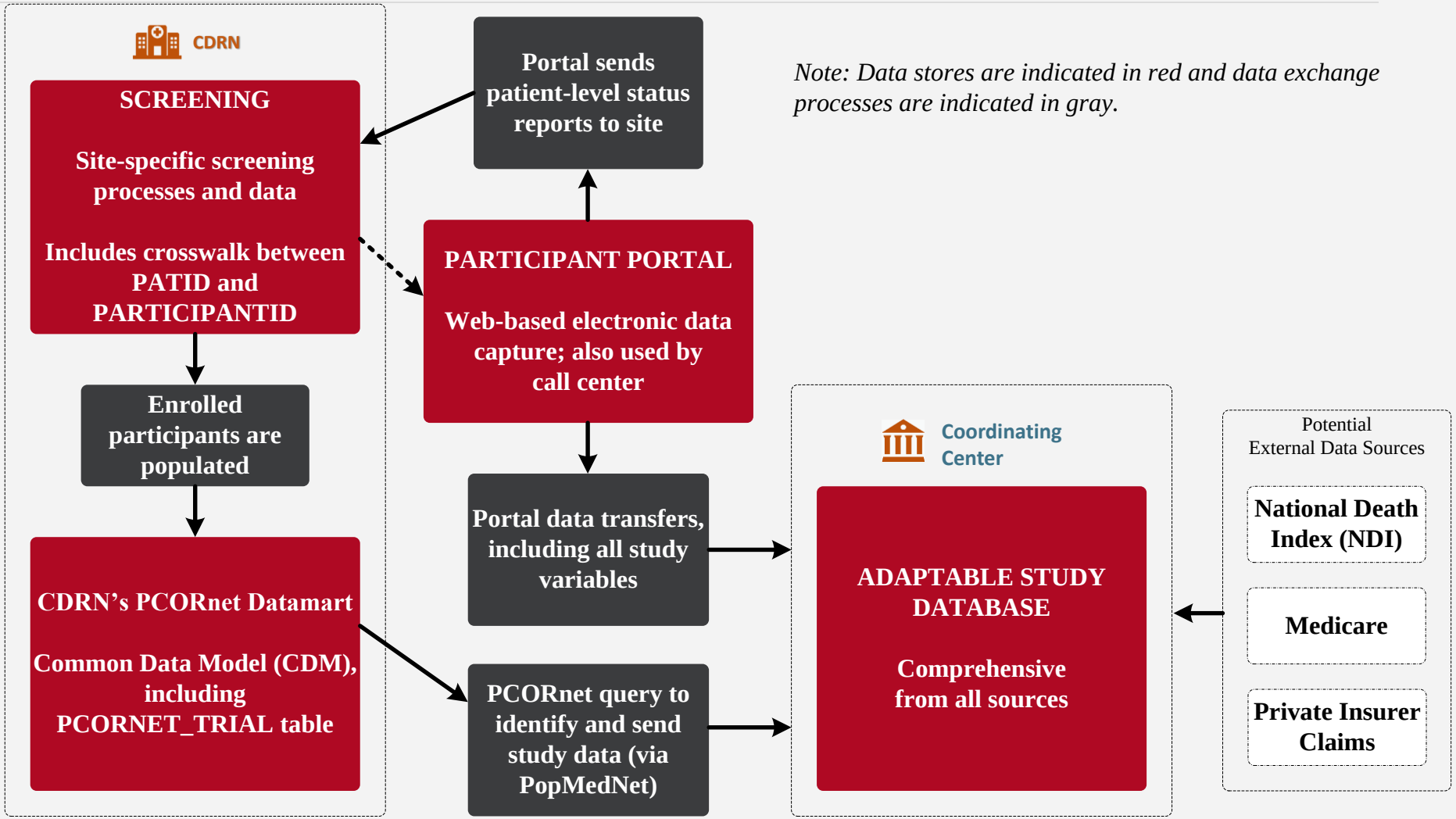


Managed at site and/or network level

*The patient answers a few basic questions to **check for those unsafe to participate**, but full eligibility criteria are determined at the site level*

Adaptable

Draft data flow diagram

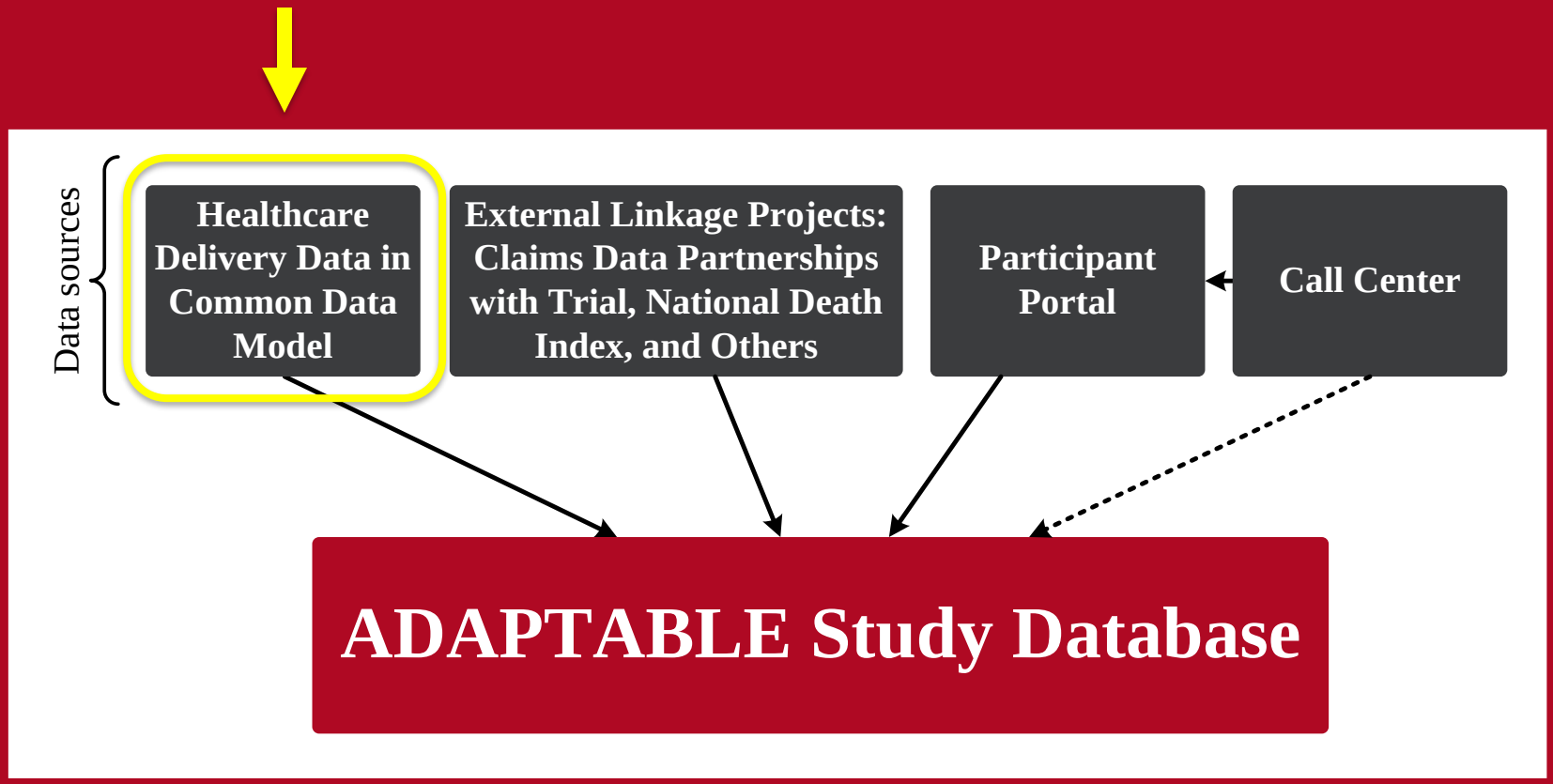


Note: Data stores are indicated in red and data exchange processes are indicated in gray.

Adaptable

Drilling Down into Individual Modules

Module #1: CDRN CDM data



#1: CDM development notes

- The ADAPTABLE trial will use CDM v3.0
- ADAPTABLE trial DRN activity will be performed in SAS
- DRN OC data characterization processes will be the primary mechanism for determining datamart “analysis-ready” state
- ADAPTABLE Site PIs will receive request to confirm ADAPTABLE datamart concordance with ADAPTABLE clinical sites

Why are “sites” different from “datamarts”?

Working definitions:

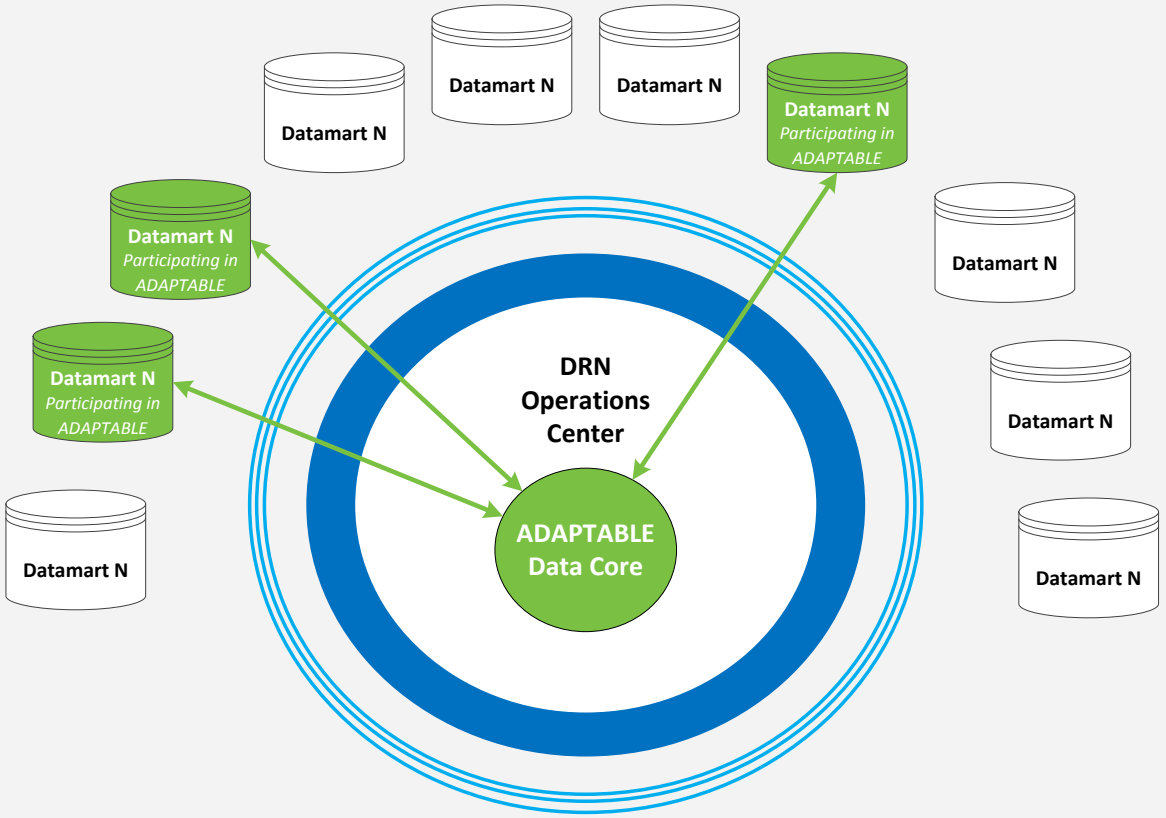
Sites = **Organization of people** for clinical and patient-facing purposes.

Datamarts = **Organization of data** for distributed querying activity.

- Existing CDRNs have different network typologies (ie, different configurations for their datamarts)
  - One datamart may include more than one site
- Sites participating in ADAPTABLE will likely be smaller components of larger networks

ADAPTABLE Distributed Querying

- Not all PCORnet datamarts will receive ADAPTABLE queries
- Only analysis-ready datamarts will populate the ADAPTABLE study database
- ADAPTABLE queries will be performed in SAS

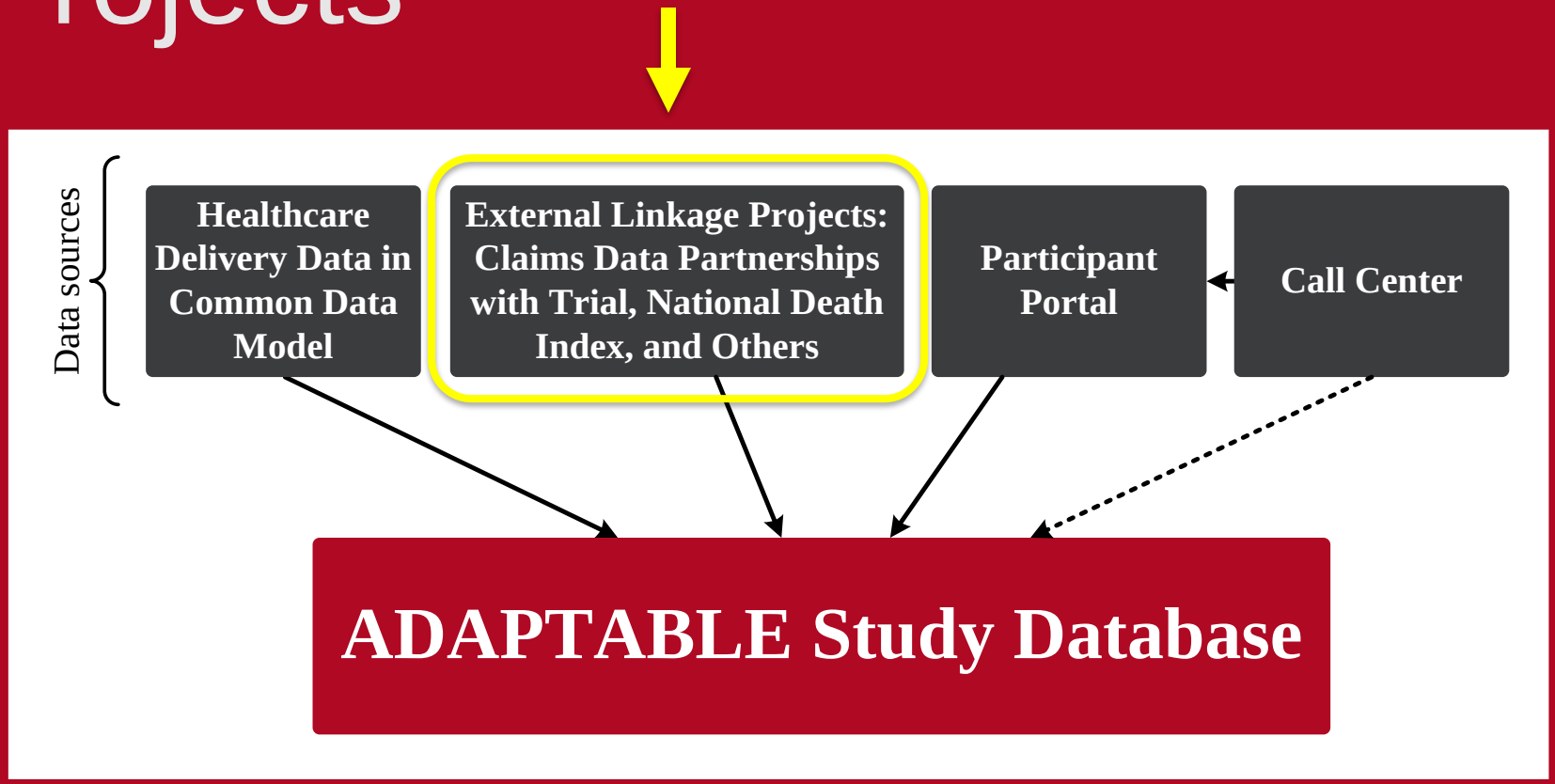


DRN Query Tool with Secure Portal (PopMedNet)

Network topology is used to direct ADAPTABLE queries to ADAPTABLE-participating datamarts

Adaptable

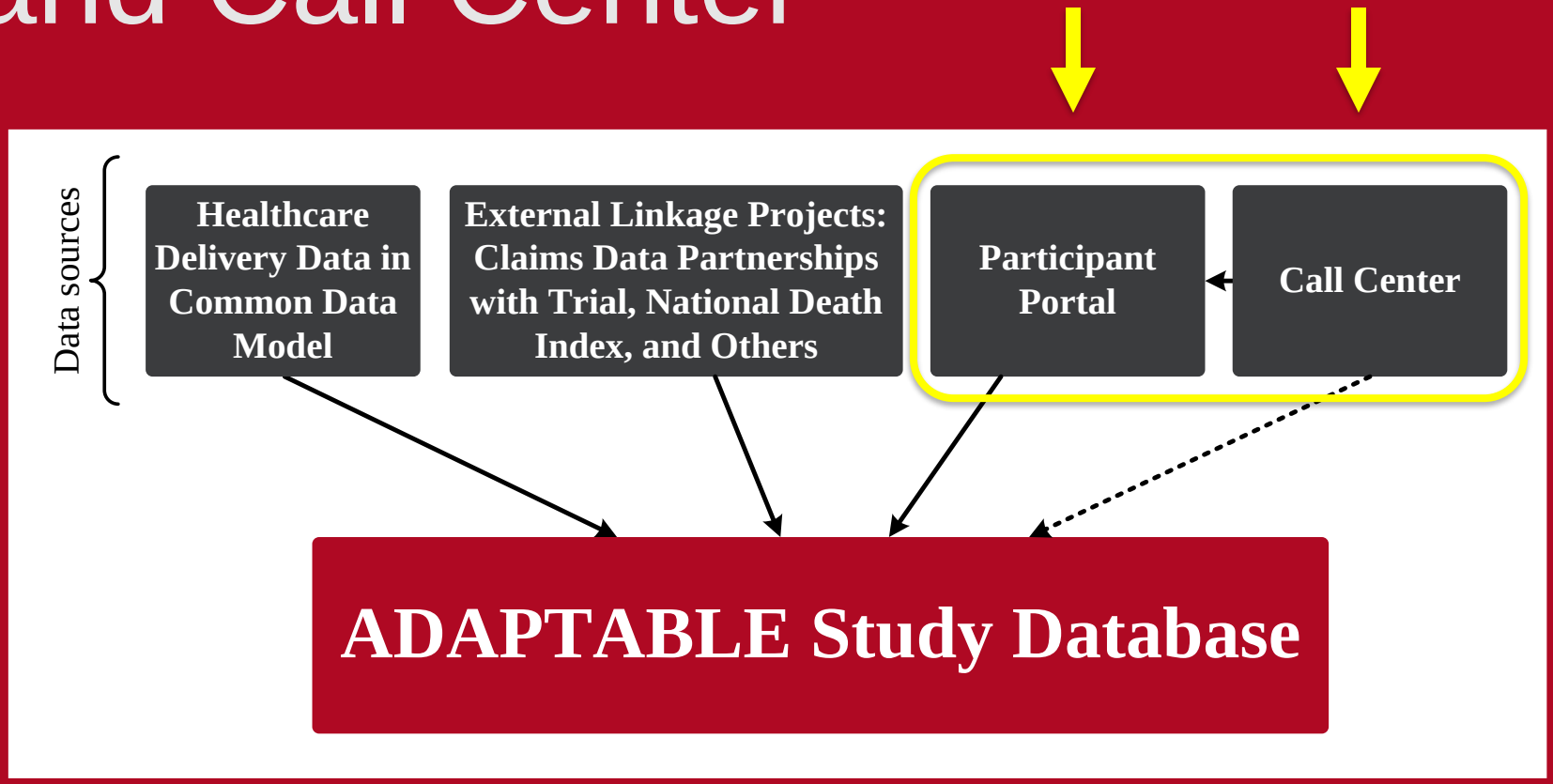
Module #2: External Linkage Projects



#2: External Linkage development notes

- Current pilot projects with GPC's Kansas University Med Ctr and Mid-South's Vanderbilt
  - Important work for developing efficient processes
- All ADAPTABLE sites will be expected to contribute patient-level identifiers for external linkage
  - These identifiers will not be exposed through the CDM; instead this will be a separate process
  - Exact details will be based upon experiences with the pilot projects

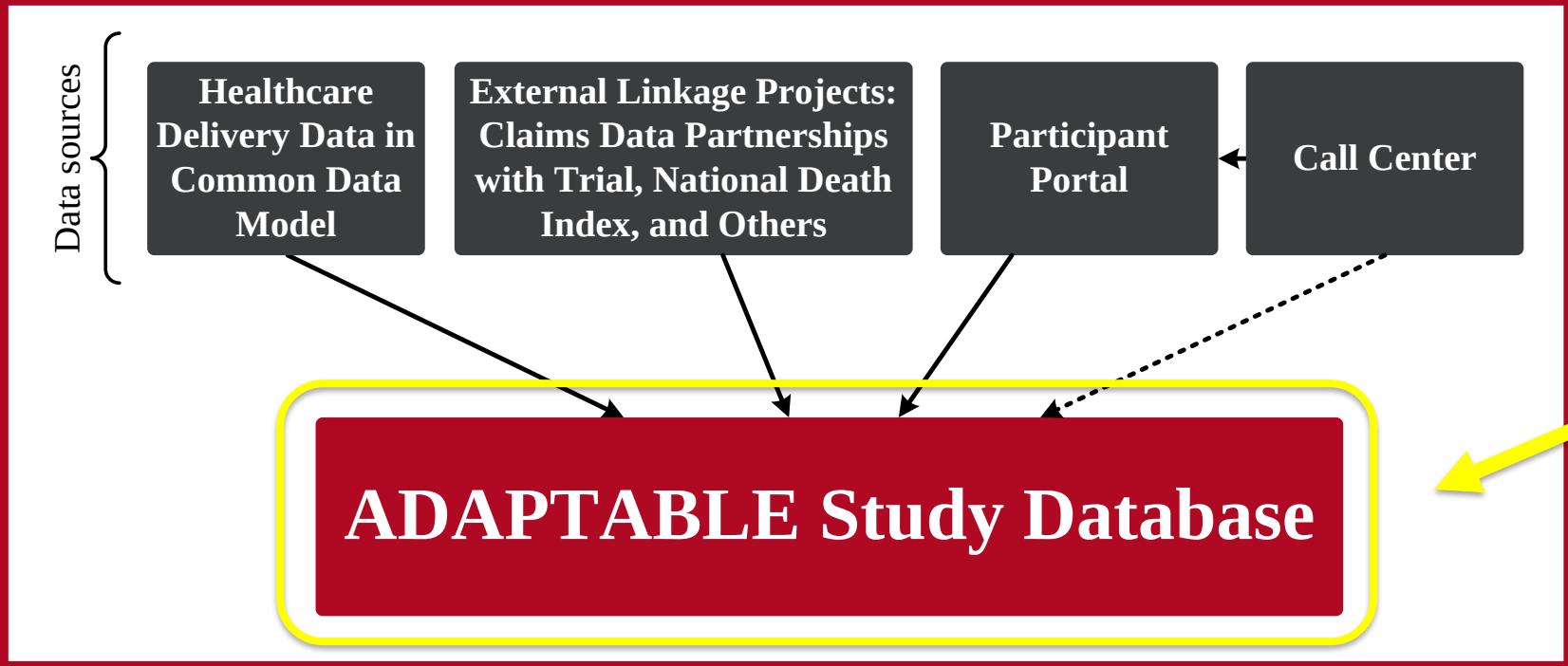
Module #3: Participant Portal and Call Center



#3: Portal and Call Center development notes

- The Participant Portal is direct patient self-report; sites are not expected to enter clinical data
- The Call Center will use the Participant Portal for follow-up of non-respondents
  - Therefore, data collection design for the Portal is consistent
- Development is underway

Module #4: Study Database



#4: Study Database development notes

- Important determinations in protocol for endpoint definitions, hierarchy of data sources, and planned analyses
- Data Safety & Monitoring Board (DSMB) reports and reviews are important process

Next steps

- Contracting, site operations, and startup
  - Weekly CDRN Calls, Mondays at 2 PM
- ADAPTABLE site PIs can expect to receive request for ADAPTABLE datamart expectations
- Follow-up ADAPTABLE data strategy meeting planned for October
- Materials from this meeting to be posted and shared
  - PCORnet weekly updates e-mail will be important mechanism to monitor

Discussion and Questions

Reference Slides

Abbreviations

- CDM = Common Data Model (http://pcornet.org/resource-center/pcornet-common-data-model/)
- DCRI = Duke Clinical Research Institute, the ADAPTABLE Coordinating Center
- DRN = Distributed Research Network
- DSMB = Data and Safety Monitoring Board
- DSSNI = Data Standards, Security, and Network Infrastructure
- LTFU = Lost to Follow-up
- RDBMS = Relational Database Management System (for example, Oracle, SQL Server, PostgreSQL, MySQL)

PCORnet Common Data Model v3.0

New to v3.0

DEMOGRAPHIC
PATID
BIRTH_DATE
BIRTH_TIME
SEX
HISPANIC
RACE
BIOBANK_FLAG

Fundamental basis

ENROLLMENT
PATID
ENR_START_DATE
ENR_END_DATE
CHART
ENR_BASIS

DISPENSING
DISPENSINGID
PATID
PRESCRIBINGID (optional)
DISPENSE_DATE
NDC
DISPENSE_SUP
DISPENSE_AMT

DEATH
PATID
DEATH_DATE
DEATH_DATE_IMPUTE
DEATH_SOURCE
DEATH_MATCH_CONFIDENCE

DEATH_CONDITION
PATID
DEATH_CAUSE
DEATH_CAUSE_CODE
DEATH_CAUSE_TYPE
DEATH_CAUSE_SOURCE
DEATH_CAUSE_CONFIDENCE

Data captured from processes associated with healthcare delivery

VITAL
VITALID
PATID
ENCOUNTERID (optional)
MEASURE_DATE
MEASURE_TIME
VITAL_SOURCE
HT
WT
DIASTOLIC
SYSTOLIC
ORIGINAL_BMI
BP_POSITION
SMOKING
TOBACCO
TOBACCO_TYPE

CONDITION
CONDITIONID
PATID
ENCOUNTERID (optional)
REPORT_DATE
RESOLVE_DATE
ONSET_DATE
CONDITION_STATUS
CONDITION
CONDITION_TYPE
CONDITION_SOURCE

PRO_CM
PRO_CM_ID
PATID
ENCOUNTERID (optional)
PRO_ITEM
PRO_LOINC
PRO_DATE
PRO_TIME
PRO_RESPONSE
PRO_METHOD
PRO_MODE
PRO_CAT

Data captured within multiple contexts: healthcare delivery, registry activity, or directly from patients

ENCOUNTER
ENCOUNTERID
PATID
ADMIT_DATE
ADMIT_TIME
DISCHARGE_DATE
DISCHARGE_TIME
PROVIDERID
FACILITY_LOCATION
ENC_TYPE
FACILITYID
DISCHARGE_DISPOSITION
DISCHARGE_STATUS
DRG
DRG_TYPE
ADMITTING_SOURCE

DIAGNOSIS
DIAGNOSISID
PATID
ENCOUNTERID
ENC_TYPE (replicated)
ADMIT_DATE (replicated)
PROVIDERID (replicated)
DX
DX_TYPE
DX_SOURCE
PDX

PROCEDURES
PROCEDURESID
PATID
ENCOUNTERID
ENC_TYPE (replicated)
ADMIT_DATE (replicated)
PROVIDERID (replicated)
PX_DATE
PX
PX_TYPE
PX_SOURCE

LAB_RESULT_CM
LAB_RESULT_CM_ID
PATID
ENCOUNTERID (optional)
LAB_NAME
SPECIMEN_SOURCE
LAB_LOINC
PRIORITY
RESULT_LOC
LAB_PX
LAB_PX_TYPE
LAB_ORDER_DATE
SPECIMEN_DATE
SPECIMEN_TIME
RESULT_DATE
RESULT_TIME
RESULT_QUAL
RESULT_NUM
RESULT_MODIFIER
RESULT_UNIT
NORM_RANGE_LOW
NORM_MODIFIER_LOW
NORM_RANGE_HIGH
NORM_MODIFIER_HIGH
ABN_IND

PRESCRIBING
PRESCRIBINGID
PATID
ENCOUNTERID (optional)
RX_PROVIDERID
RX_ORDER_DATE
RX_ORDER_TIME
RX_START_DATE
RX_END_DATE
RX_QUANTITY
RX_REFILLS
RX_DAYS_SUPPLY
RX_FREQUENCY
RX_BASIS
RXNORM_CUI

Data captured from healthcare delivery, direct encounter basis

PCORNET_TRIAL
PATID
TRIALID
PARTICIPANTID
TRIAL_SITEID
TRIAL_ENROLL_DATE
TRIAL_END_DATE
TRIAL_WITHDRAW_DATE
TRIAL_INVITE_CODE

Associations with PCORnet clinical trials

HARVEST
NETWORKID
NETWORK_NAME
DATAMARTID
DATAMART_NAME
DATAMART_PLATFORM
CDM_VERSION
DATAMART_CLAIMS
DATAMART_EHR
BIRTH_DATE_MGMT
ENR_START_DATE_MGMT
ENR_END_DATE_MGMT
ADMIT_DATE_MGMT
DISCHARGE_DATE_MGMT
PX_DATE_MGMT
RX_ORDER_DATE_MGMT
RX_START_DATE_MGMT
RX_END_DATE_MGMT
DISPENSE_DATE_MGMT
LAB_ORDER_DATE_MGMT
SPECIMEN_DATE_MGMT
RESULT_DATE_MGMT
MEASURE_DATE_MGMT
ONSET_DATE_MGMT
REPORT_DATE_MGMT
RESOLVE_DATE_MGMT
PRO_DATE_MGMT
REFRESH_DEMOGRAPHIC_DATE
REFRESH_ENROLLMENT_DATE
REFRESH_ENCOUNTER_DATE
REFRESH_DIAGNOSIS_DATE
REFRESH_PROCEDURES_DATE
REFRESH_VITAL_DATE
REFRESH_DISPENSING_DATE
REFRESH_LAB_RESULT_CM_DATE
REFRESH_CONDITION_DATE
REFRESH_PRO_CM_DATE
REFRESH_PRESCRIBING_DATE
REFRESH_PCORNET_TRIAL_DATE
REFRESH_DEATH_DATE
REFRESH_DEATH_CAUSE_DATE

Process-related data

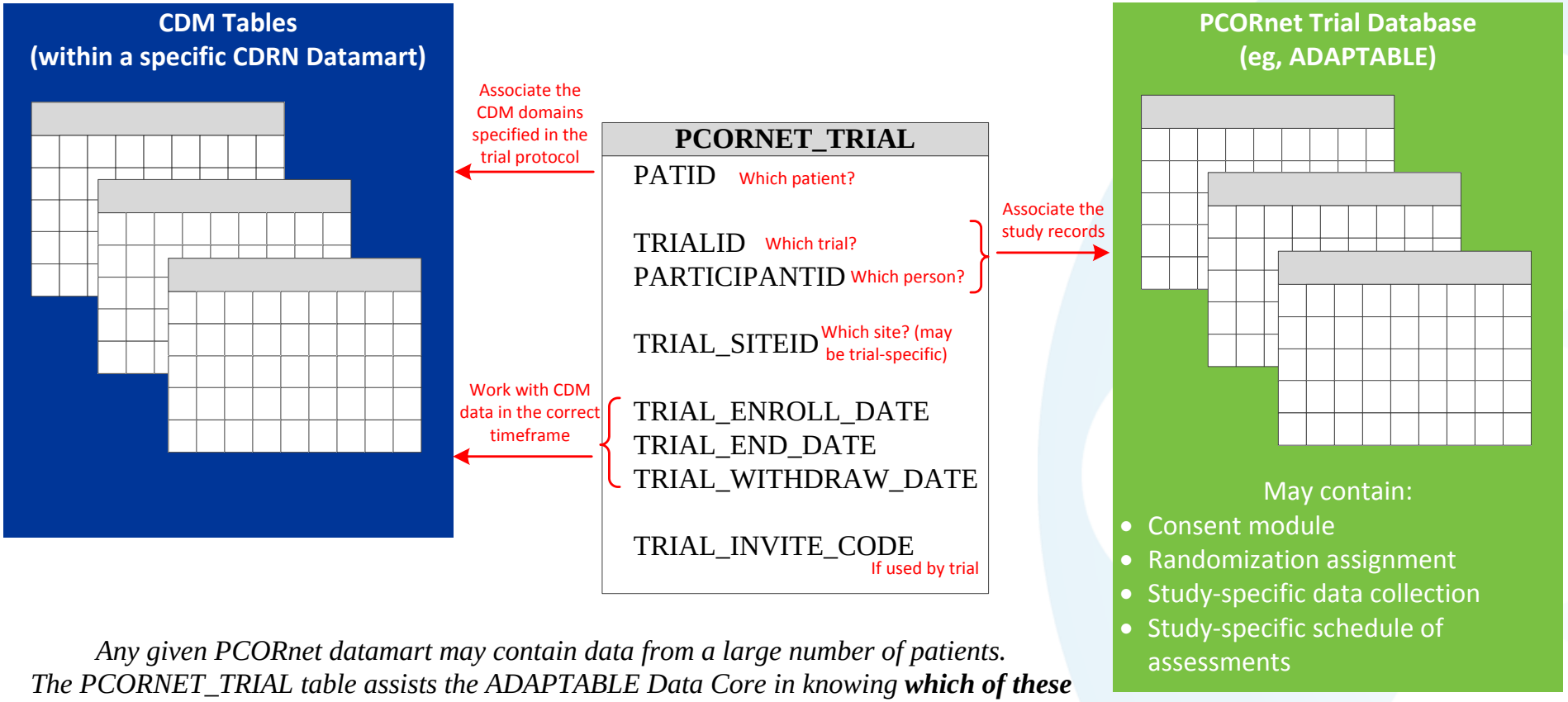
http://www.pcornet.org/resource-center/pcornet-common-data-model/

Bold font indicates fields that cannot be null due to primary key definitions or record-level constraints.

pcornet

The PCORnet CDM lives at
http://pcornet.org/pcornet-common-data-model/

The PCORNET_TRIAL table serves as a connector and filter for CDM data within the parameters of a given trial protocol:



Any given PCORnet datamart may contain data from a large number of patients. The PCORNET_TRIAL table assists the ADAPTABLE Data Core in knowing ***which of these patients have consented and been enrolled*** *in the ADAPTABLE trial for querying purposes.*

pcornet