Decentralized Clinical Trials
Data Flow Maps

ACRO Decentralized Clinical Trials Working Party
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Note to Reader

Data integrity and data control are key pillars of clinical research. These maps are designed to illuminate and explain how the data flow within five key processes in a decentralized clinical trial.

Please note that this is a dynamic and living document. We will continue to revise and refine these maps as needed and welcome stakeholder feedback.

This document is not intended to be a “stand-alone” tool. Rather, it is one element of the ACRO Decentralized Clinical Trials Toolkit. The DCT Toolkit consists of four resources:

- *Bringing the Trial to the Patient: A Quality-by-Design Manual for Decentralized Clinical Trials*
- *Decentralized Clinical Trials Risk Assessment Considerations*
- *Decentralized Clinical Trials Data Flow Maps*

The complete ACRO DCT Toolkit can be found on the website at: [www.acrohealth.org/dct](http://www.acrohealth.org/dct)
**eConsent**

**Participant**
(Continuous access to the eConsent system or paper copy)

**eConsent Device**
- Data containing the signed eICF and data protection documents and consent & permission status

**Vendor eConsent Cloud**
- Subject number and some demographic data, date/time of consent and version of consent(s) signed

**EDM/RTSM/CTMS**
- EDM (Electronic Data Management)/RTSM (Randomization and Trial Supply Management)/CTMS (Clinical Trial Management System)
- Data containing the signed eICF and data protection documents

**Site File Storage**
- Optional Biosample Use Consent Information
- Archival Data containing Opt In/Out Consent for future use of Biosamples

**LIMS**
- Laboratory Information Management System

**Current Biosample Holder Data Depository**
(Barcode/RFID technology)

**Dates and confirmation of EC/HA approval of the amendment should be synchronised on a country site level**
• Participant always has continuous access to the eConsent system or paper informed consent form (ICF) copy

• Participant interacts with the **eConsent device**, to become familiar with trial information and the electronic informed consent form (eICF)

• Data containing the signed eICF, data protection documents, and consent & permission status are synchronized between the **Vendor eConsent Cloud** and the **eConsent Device**

• Data containing amendments, revisions, dates, and confirmation of Ethics Committee/Health Authority (EC/HA) approval of the amendment are synchronized on a country/site level – and are also synchronized between the device and the eConsent cloud – to ensure the most up-to-date and correct information is displayed

• Subject number and some demographic data – as well as data on the date/time of consent and version of consent(s) signed – are transferred from the **Vendor eConsent Cloud** into Electronic Data Management/Randomization and Trial Supply Management/Clinical Trial Management System (EDM/RTSM/CTMS)

• Data containing the signed eICF and data protection documents are directed to the **Site File Storage** system

• Optional Biosample Use Consent Information (obtained from the **eConsent Device** and synchronized onto the **Vendor eConsent Cloud**) is uploaded into Laboratory Information Management System (LIMS) – either directly from the **eConsent Cloud** or via the **EDM/RTSM/CTMS** systems

• The archival data containing Opt In/Out Consent for future use of Biosamples are directed to the **Current Biosample Holder Data Depository** where barcode or RFID Technology may be used to identify the opt in/out consent option selected by the participant which is synchronized with the previous systems such as the **eConsent Cloud** and **EDM/RTSM/CTMS**, which feed the data into the **LIMS**
Direct-to-Patient Supply of IP

**eConsent**
Confirm the subject consented to IP shipment

**Synchronization**

**Depot System**

**Supply Depot**

**Certified Courier Network**

**Home Healthcare Nurse**

**Local Site**

**Local Pharmacy**

**Site**
(Virtual or Brick & Mortar)

**RTSM**

**Participant Shipping Details**

**Participant**

**Shipping Details**
Which IP to ship to which participant

**Patient IP receipt/return information**
(for drug accountability)

**Participant**

**Shipping Details**

**Packer and Courier blinded to PHI, but not to PII**

**Study Database**

**Site/Pharmacy/HHN acknowledgement of IP receipt/return information**

**Data on Participant Compliance with IMP self-administration**

**ePRO**

**Participant acknowledgement of IP receipt/return information**

**ACRO DCT Data Flow Maps**
Direct-to-Patient Supply of IP

- The site (virtual or brick & mortar) holds the data regarding Participant Shipping Details, which is fed into the RTSM.

- Confirmation of consent triggers IP shipment – this includes both (a) confirmation that subject has consented to trial participation and (b) confirmation that subject has consented to sharing of their personal information with the IP depot/courier and agrees to DtP shipment.

- The consent data feeds into the RTSM platform (as described in the previous eConsent graphic).

- The information regarding which Investigational Product (IP) to ship to which participant is synchronized between RTSM, the Depot System and the Supply Depot.

- From the Supply Depot, the participant shipping details are transferred to the Certified Courier Network, where packers and couriers are blinded to the personal health information (PHI), but not the personally identifiable information (PII).

- From the Certified Courier Network, the IP is delivered to the participant, either via direct delivery, or through a local pharmacy, home healthcare nurse or a local site.

- Upon delivery, patient acknowledgement of IP receipt/return information and Patient IP receipt/return information (for drug accountability) are fed into the RTSM.

- Data on Participant Compliance with IP self-administration may be entered by the patient into an ePRO application, feeding into the Study Database, which transfers the data back to the site.
Investigator-Participant Interactions

Study Management Platform

Notes and clinical observations from Site Staff

Bilateral Communication
(Face-to-Face, Telemedicine, Text, Chat, Telephone, etc.)

Alerts & Reminders

Site

Site Source System
(EHR/eSource)

EDM/DDC
(Electronic Data Management/ Direct Data Capture)

Participant
Investigator-Participant Interactions

- Data on scheduling of face-to-face or televisits from site are fed into the **Study Management Platform**, which sends out alerts and reminders to the participant.

- **Bilateral communication** (via the mode of Face-to-face, Telemedicine, Text, Chat, Telephone, or other) connects the site to the participant and facilitates the flow of data.

- The data on the completion, and details of the interactions are synchronized between the site and the **Electronic Data Management (EDM)/Direct Data Capture (DDC)**, and from the site are sent to the **Site Source System** (EHR or eSource).
Connected Devices

- Wearables and Sensors for data capture
- Participant receives wearable/sensor
- Raw data collected by sensor
- Algorithm for data processing
- Data processed and standardized in the Product Cloud
- Optional return of data from the sensors
- Participant inputs data into application
- ePRO Application
- Site Staff
- EDM
• Participant enrolls into trial and receives connected devices in the form of the **wearables/sensors** for data capture and/or the **ePRO application** (on a personal or provisional device)

• Raw data collected by the wearables/sensors are queried using the algorithm for data processing, and later the data are processed and standardized in the **Product Cloud**

• The data input by the participant into ePRO is also processed and standardized in the **Product Cloud**.

• From here, the data on ePRO inputs and wearables/sensors are directed to site staff, and later into the **EDM**
Home Health Visits

- Site
  - Patient Registration Information

- Health Practitioner
  - at Participant Location

- Participant

- eCOA
  - Participant Study Data

- Telemedicine

- Logistics Courier
  - for IP delivery

- RTSM
  - (confirm receipt and dispensation of IP)

- eISF

- (e)Source Data

- EDM
Home Health Visits

- From the **site**, patient registration information is directed to the **health practitioner** at the **participant's location**

- During the home health visit, the health practitioner inputs participant study data directly into **eSource data** which feedbacks to the site

- Alternative to (or in conjunction with) direct entry into eSource by the **health practitioner**, the data collected during home health visits may be directed into eSource Data, or into the electronic investigational site file (eISF) or the EDM via other **medical/wearable devices, eCOA inputs from the practitioner, telemedicine information, or logistics courier and RTSM for IP delivery**

- **eSource data** can also directly feed into the **eISF or the EDM** – and, ultimately, the **eSource data** is fed back to the site