



# 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.

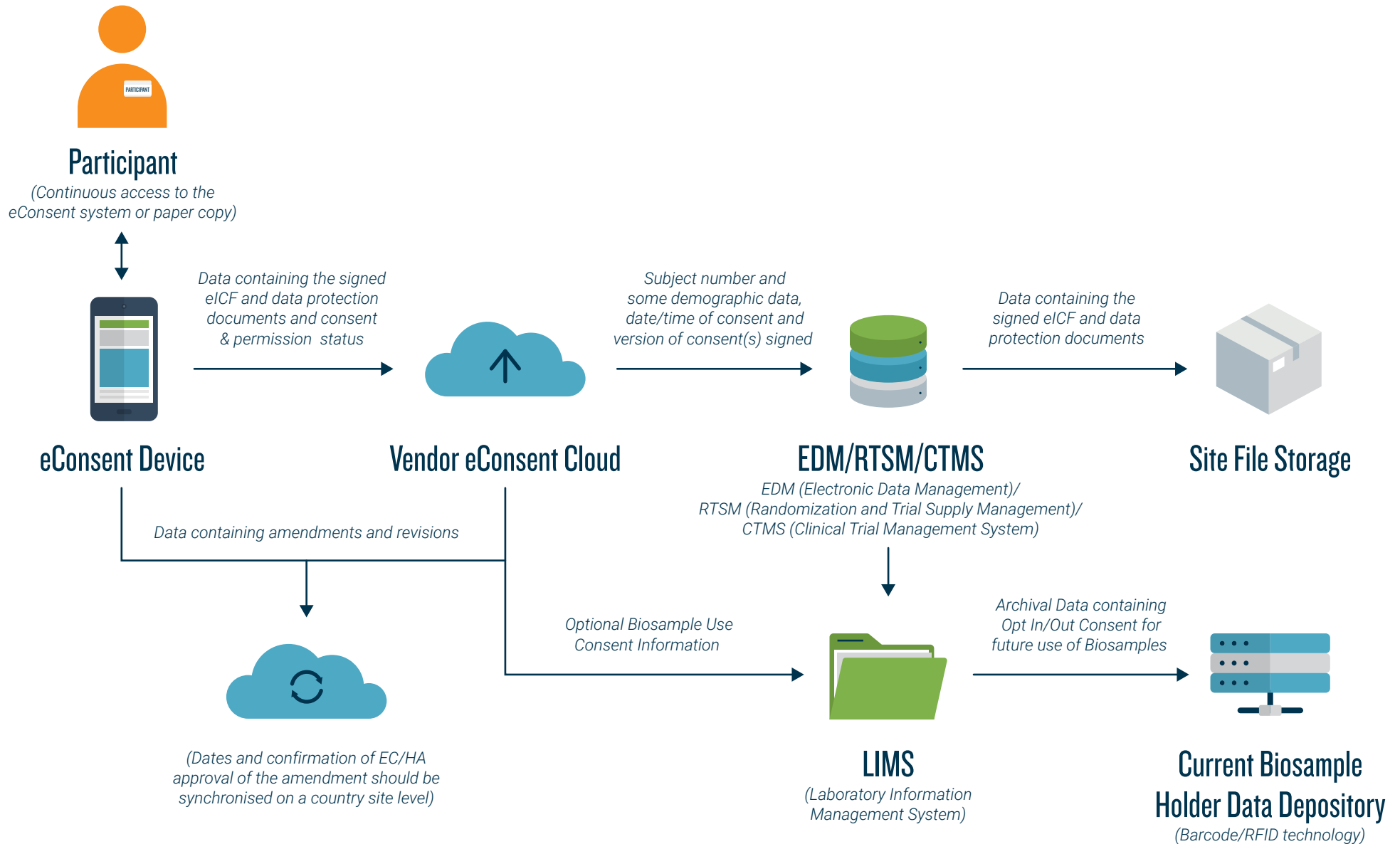
Please note that this is a dynamic and living document. We will continue to revise and refine these maps as needed and welcome stakeholder feedback.

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*
- *QbD Manual for Decentralized Clinical Trials – The Quick Reference Guide*
- *Decentralized Clinical Trials Data Flow Maps*

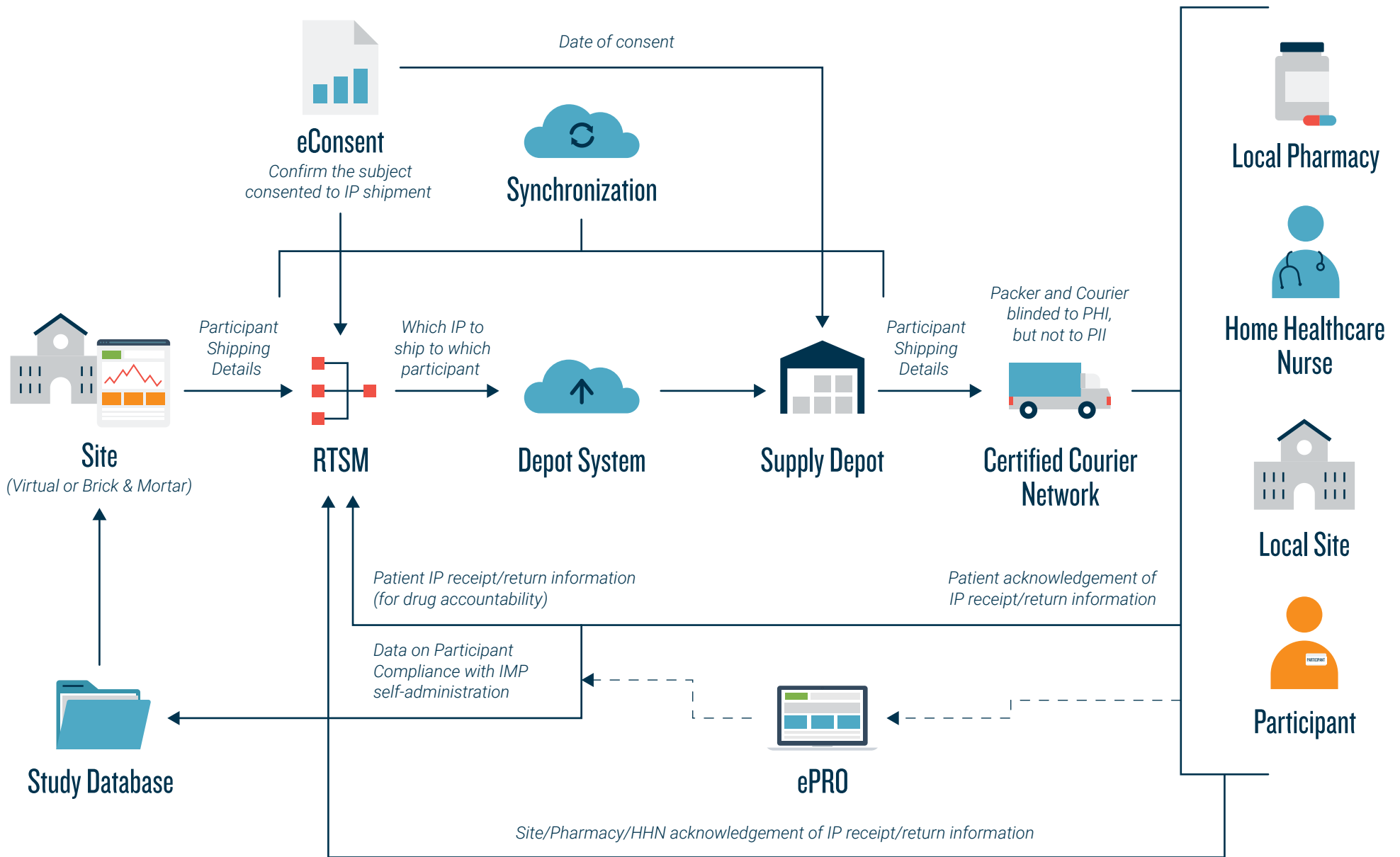
The complete ACRO DCT Toolkit can be found on the website at: [www.acrohealth.org/dct](http://www.acrohealth.org/dct)

# eConsent



- Participant 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**

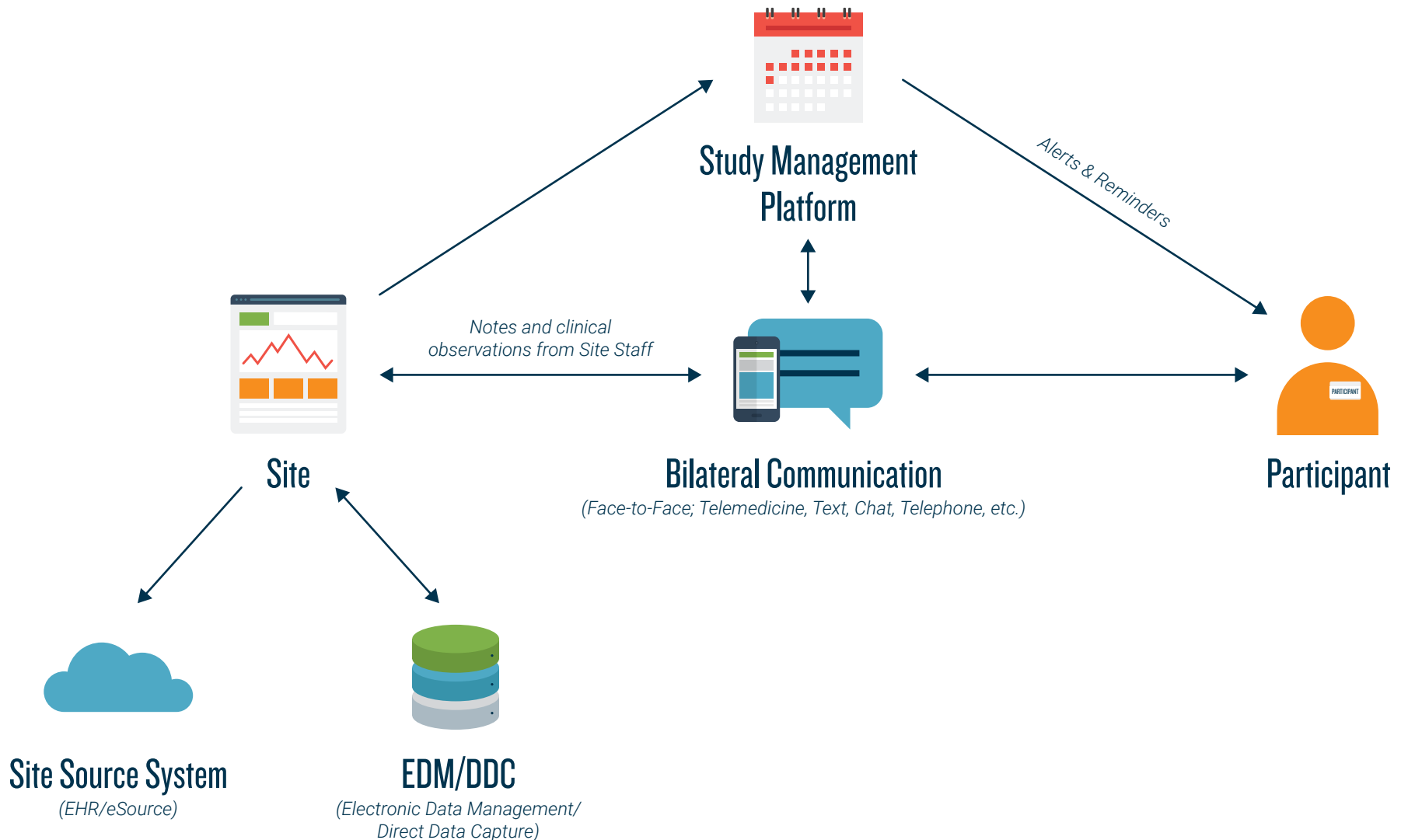
# Direct-to-Patient Supply of IP



# 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

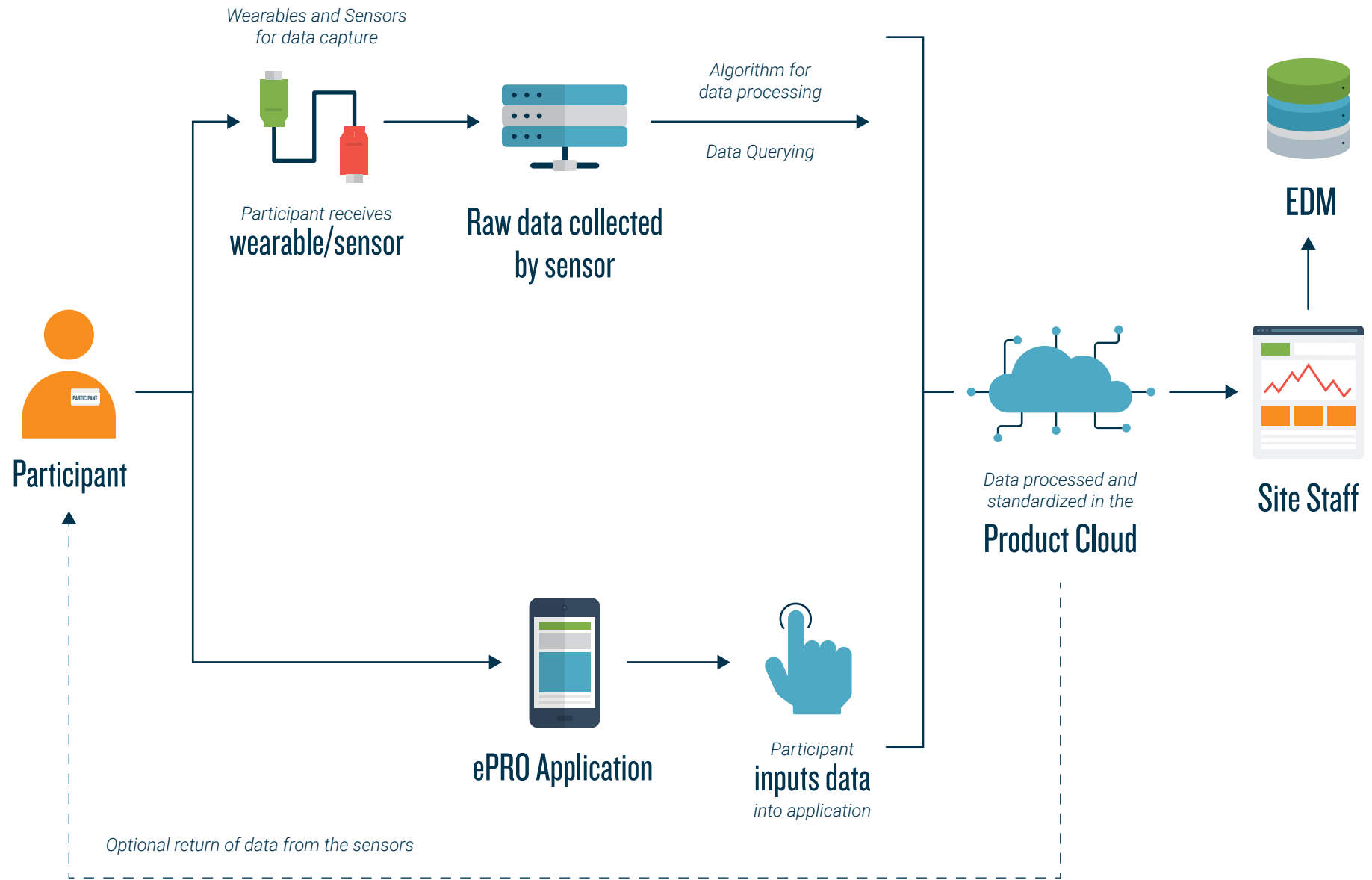


# Investigator-Participant Interactions

- 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)



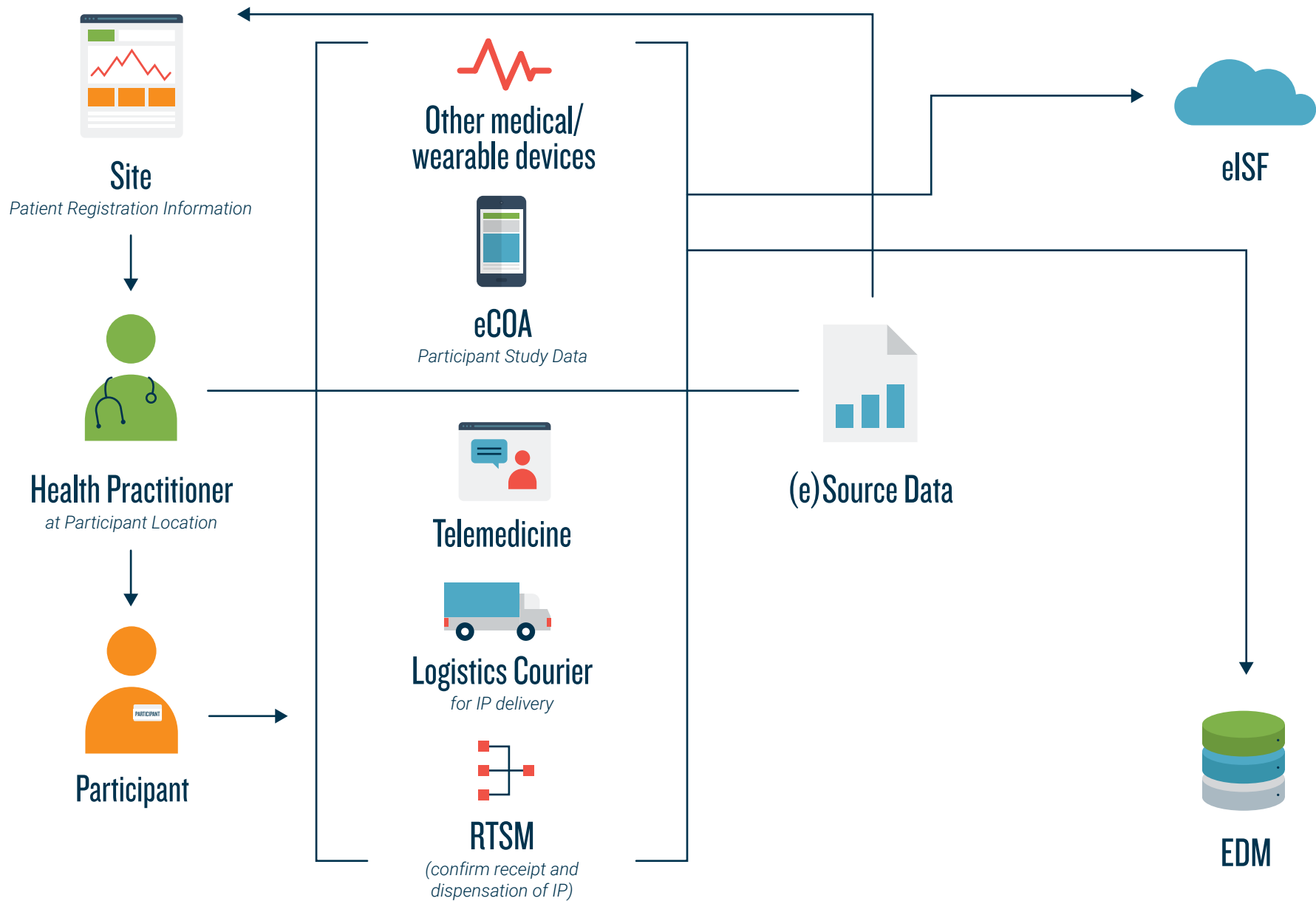
# Connected Devices



# Connected Devices

- 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



# 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 feeds back 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

# ACRO Decentralized Clinical Trials | Complete Map

