ALMAC

Partnering to Advance Human Health

Fact Sheet

IXRS®3 Decentralised Trials Support

Direct-to-Patient supply management



Decentralised Trials (DCT) - Direct to patient benefits

Direct to patient shipment functionality provides the ability for a site to register a visit with home delivery of investigational material. This type of protocol design can help with:

- Patient retention by lessening the burden of traveling to every dispensing site visit
- Prevention of wasted investigational material at sites with low or no enrollment
- Agility for a changing supply chain landscape



Almac IXRS®3 DCT support

IXRS®3 IRT platform provides the necessary flexibility for today's trials supporting a variety of patient assignment methodologies.

Beyond the traditional drug assignment from site inventory with subsequent on-site dispensing; introduction of DCT methodologies allows assignment and then shipment of patient supply originating from inventory stocked at a depot or site location.

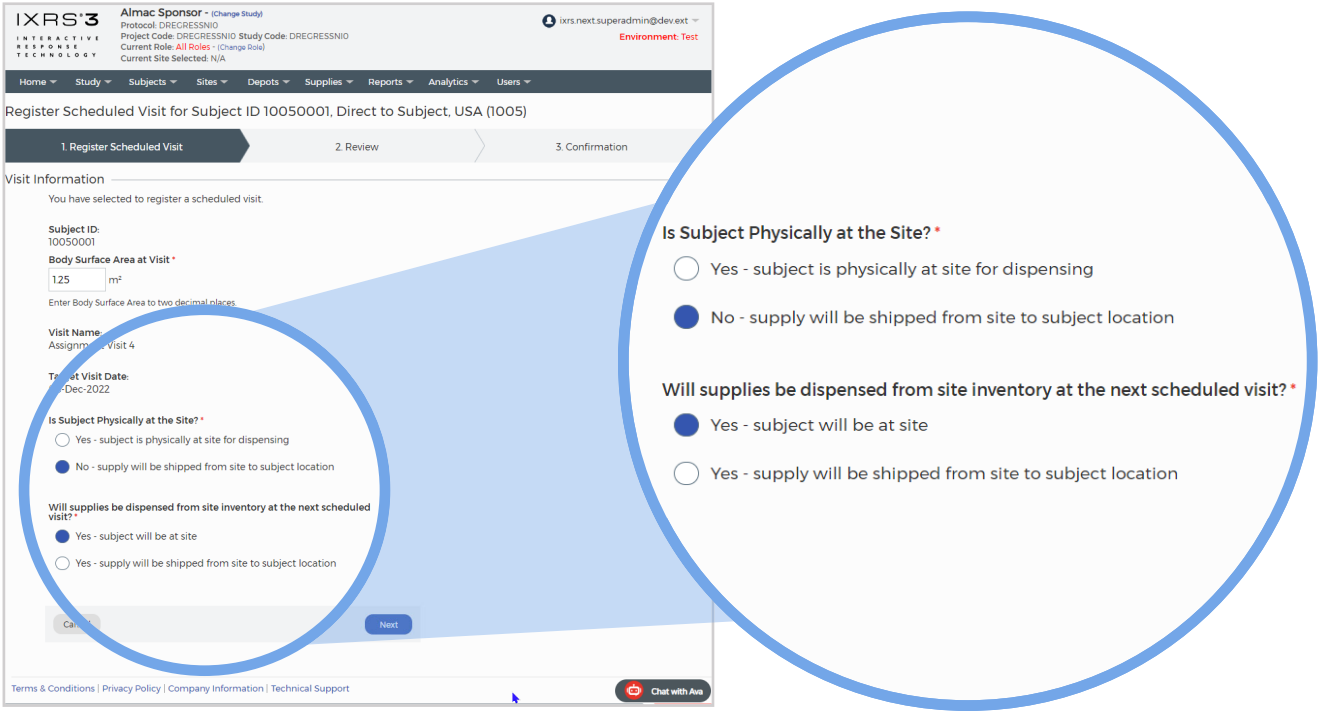
These methodologies can be tailored per the protocol design and further defined for any country, depot, site, visit or patient level capabilities, restrictions or preferences.

DCT support features available through IXRS®3

Study configuration flexibility
IXRS®3 includes configurations to define what direct to patient methodologies are permitted at various levels: study, country, site and depot. Further, the drug assignment visit schedule will account for any visits where direct to patient assignments are not allowable. These settings can be altered during the course of the study as needed.

Drug assignment visits
Based on the study settings, IXRS®3 allows the site to designate how the subject will receive investigational material when registering the drug assignment visit. Expectations for the next visit's dispensing methodology is also collected to ensure adequate site inventory levels.

Drug replacement
In the event supply is deemed unacceptable for use at the time of delivery or at any point that requires replacement, the kit replacement feature can be utilised by the site. Kit replacement gives the site the option to ship the new product directly to the patient or dispense at the site or from the site inventory.

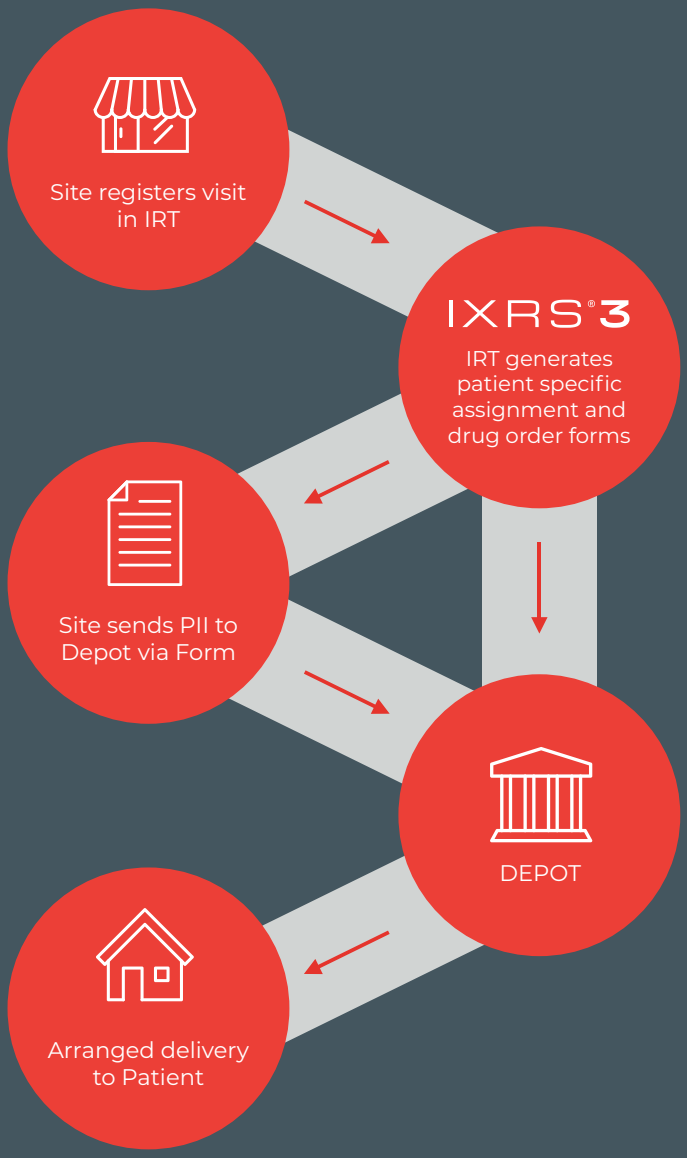


Factors for consideration for sponsors, clients, and depots when choosing a decentralised supply dispensing approach:

- Multiple parties may require involvement in supporting at home dispensing. Couriers may need the ability to report shipment temperature conditions. Home health aides may need to assist with reporting actual dispensing or product replacement.
- Depots may require on-site pharmacists to fill the role occupied by site personnel in verifying investigational material being sent to patients.
- Differing country regulations allowing shipment of investigational material directly to patients.
- Assurance that PII (personally identifiable information) covered under HIPAA and similar regulations is handled appropriately by those needing it for shipment handling like depots and couriers.
- Limitations and abilities of private couriers in delivering an investigational product to patients and determining the condition of the product before providing it to patients.

- Direct-to-Patient shipments are designated by the site staff at visit registration as allowed by study configurations
- Drug order(s) are provided to the depot for the patient specific supply assignment for shipment
- Site provides the patient's mailing address and preferred delivery date/time directly to the depot via the IXRS-provided blinded drug order form

Depot to Patient Workflow



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