Direct to Patient Webinar

Lisa Falzone
Pamela Osborne
Dave Ergott
Mike Sweeney
Neta Bendelac
Henk Dieteren
Steve Jacobs
Terrence Walsh
Nicole Gray

GLOBAL CLINICAL SUPPLIES GROUP

GATHER. COLLABORATE. SHARE. GROW.

Meet the Team

Nicole Gray – Moderator

Nicole is a clinical supplies consultant with over 20 years of experience in CRO and CDMO organizations. She formerly led the Decentralized Trial Solutions at a top CDMO for eight years. Nicole is also the Conference Chair for the GCSG US 2026 Conference in San Diego.

Pam Osborne - Presenter

Pam brings over 27 years of supply chain experience, including 18 years in clinical supply for pharmaceutical companies and biotechs. Pam has supported global direct to patient studies and most recently creating a standardized DTP process for a small biotech.

Lisa Falzone – Presenter

With more than 20 years in the pharmaceutical industry, Lisa specializes in Direct-to-Patient clinical supply distribution. She has led global DTP programs, created standardized processes, and has been GCSG's DTP Team Lead since 2021.

Dave Ergott - Presenter

Dave has over 15 years of experience in healthcare supply chain. He currently serves as a Supply Chain Solutions Manager at Almac Clinical Services, responsible for advancing the Almac to Patient service.

Meet the Team

Henk Dieteren - Presenter
Henk has over 30 years of experience in Clinical Operations and Clinical Trial Supplies, specializing in innovative technologies such as IRT, temperature excursion management, and direct-to-patient logistics.

Mike Sweeney - Presenter
Mike brings over 30 years of experience in specialty logistics for global clinical trials and life sciences. He has overseen direct-to-patient programs in 50+ countries and is now QuickSTAT's Global Head of Strategy.

Neta Bendelac - Presenter
With over 18 years in Clinical Supply Chain Management, Neta has led clinical supply for global pharma companies. She now manages Strategic RTSM clients at 4G Clinical, driving innovation and product development.

Steve Jacobs – Team Member
Steve, with 30 years in the industry, serves on the GCSG Board of Directors. He is a consultant experienced in clinical supplies and currently supports one active DTP client, overseeing setup and ongoing global program support.

Terrence Walsh – Team Member
Terry brings 35+ years in drug development experience, focusing on clinical supply chain, oncology trials, and comparator sourcing. He is Director of Comparator Strategy at Regeneron Pharmaceuticals and a licensed pharmacist who works weekends at a local pharmacy.

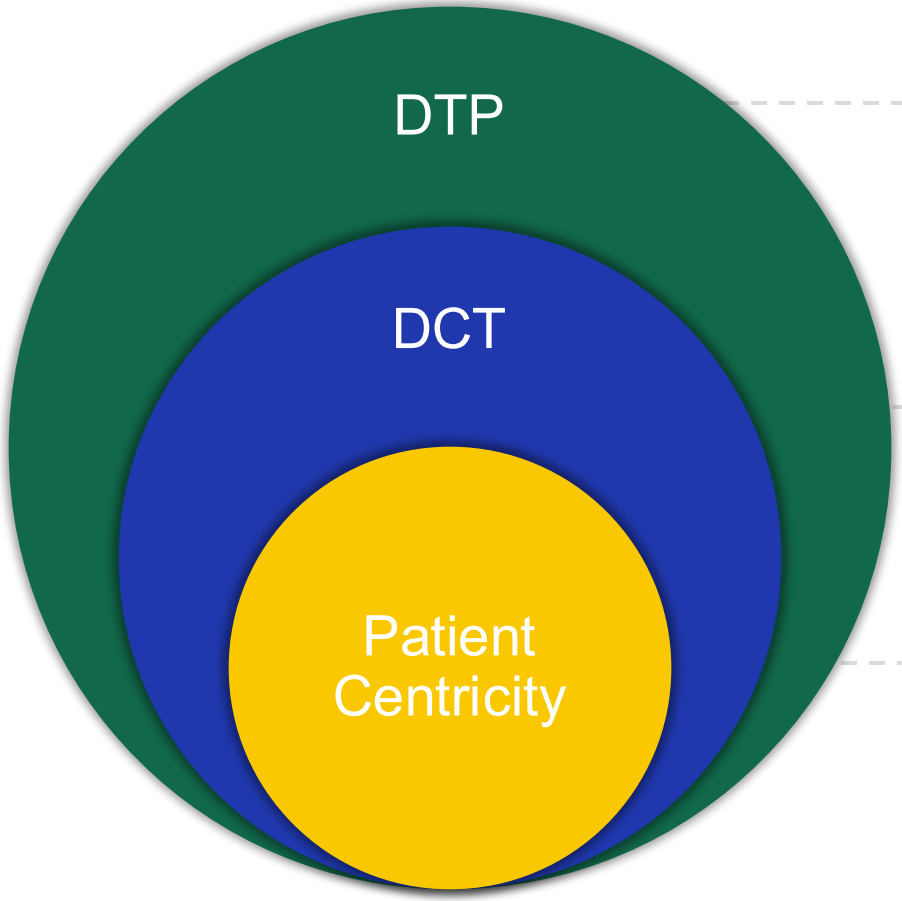
Industry Facts

85% of trials are delayed, leading to unexpected costs

90% of trials exceed allotted budget

< 5% of population participates in clinical trials

Terms and Definitions



Direct to Patient (DTP)
An element of decentralized clinical trials where investigational product (IP) is delivered directly to a patient's home

Decentralized Clinical Trial (DCT)
One or more aspects of clinical trial conduct takes place away from physical site, increasing patient centricity

Patient Centricity
Improving the patient experience by reducing complexity and burden while participating in a clinical trial

DTP helps close the gap

Studies show Investigator and Patient feedback

85%

of **patients** indicated that they were more likely to participate if DTP shipping were offered

90%

of **sites** indicated willingness to participate in clinical trials that offer DTP shipments

40%

Sponsor ROI in direct cost savings (based on industry averages) from time saved in phase III clinical trial and averaged direct costs

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

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SITE Receptivity to Direct-to-Patient Shipment in Clinical Trials - GCSG

PATIENT Receptivity to Direct-to-Patient Shipment in Clinical Trials - GCSG

Poll the Audience

Question: What is the primary driver pushing your team to consider DTP strategies?

A. **Recruitment & Diversity:** Reaching populations far from sites/rare diseases.

B. **Retention:** Reducing dropout rates by lowering patient burden.

C. **Patient Preference:** Meeting the demand for convenience/home-based care.

D. **Rescue:** Using DTP as a contingency for missed visits or emergency situations.

DTP Models

Top 3 DTP Models

- Site to Patient
- Pharmacy to Patient
- Depot to Patient

Site to Patient

- Kits dispatch from clinical site
- Site prepares kit and coordinates with patient and provider for delivery
- High Site Burden
- Health Authorities Preferred

DTP Models

Top 3 DTP Models

Site to Patient

Pharmacy to Patient

Depot to Patient

Pharmacy to Patient

- Kits dispatch from central pharmacy
- Shipments may be subject to local pharmacy laws (including state or province)
- May require signed Prescription
- Pharmacy prepares kits
- Less Burden for Site Staff

DTP Models

Top 3 DTP Models

Site to Patient

Pharmacy to Patient

Depot to Patient

Depot to Patient

- Depot managed distribution (GDP)
- Supply Efficient
- Not broadly accepted by Health Authorities

Poll the Audience

Question: Where does your organization currently stand on the DTP adoption curve?

A. **Novice:** We are just learning/exploring; no active DTP trials yet.

B. **Experimental:** We have run 1–2 pilots or hybrid trials.

C. **Operational:** We have a standard process and multiple DTP trials running.

D. **Advanced:** DTP is our default approach for suitable protocols.

Sponsor Roadmap

Stakeholder Alignment

Process Alignment

Implementation

Sponsor Roadmap

Stakeholder Alignment

Identify Stakeholders

Align key goals

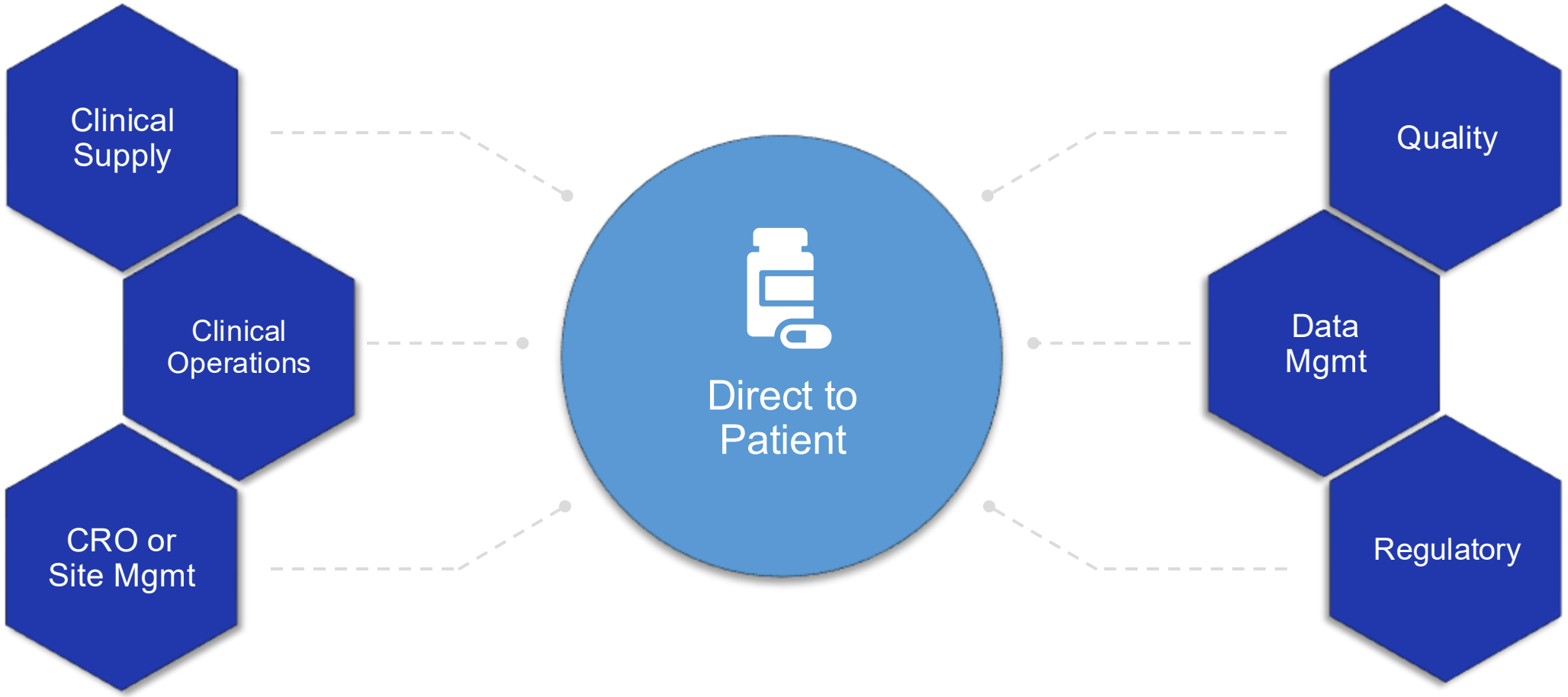
Identify Process owner

Process Alignment

Implementation

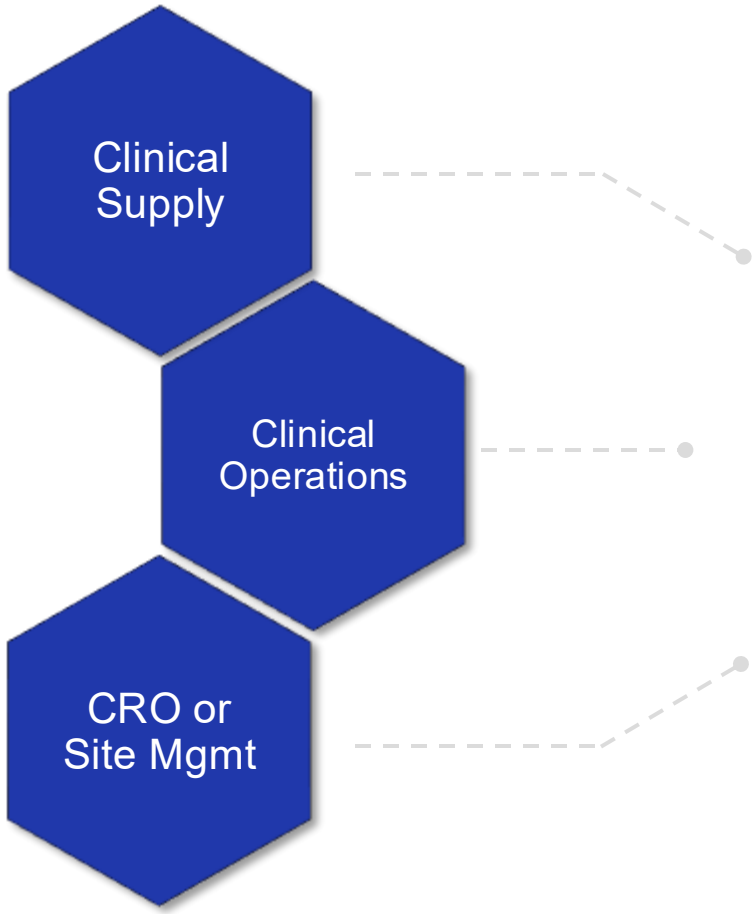
Stakeholder Alignment

Internal Stakeholders



Stakeholder Alignment

Internal Stakeholders



Goals

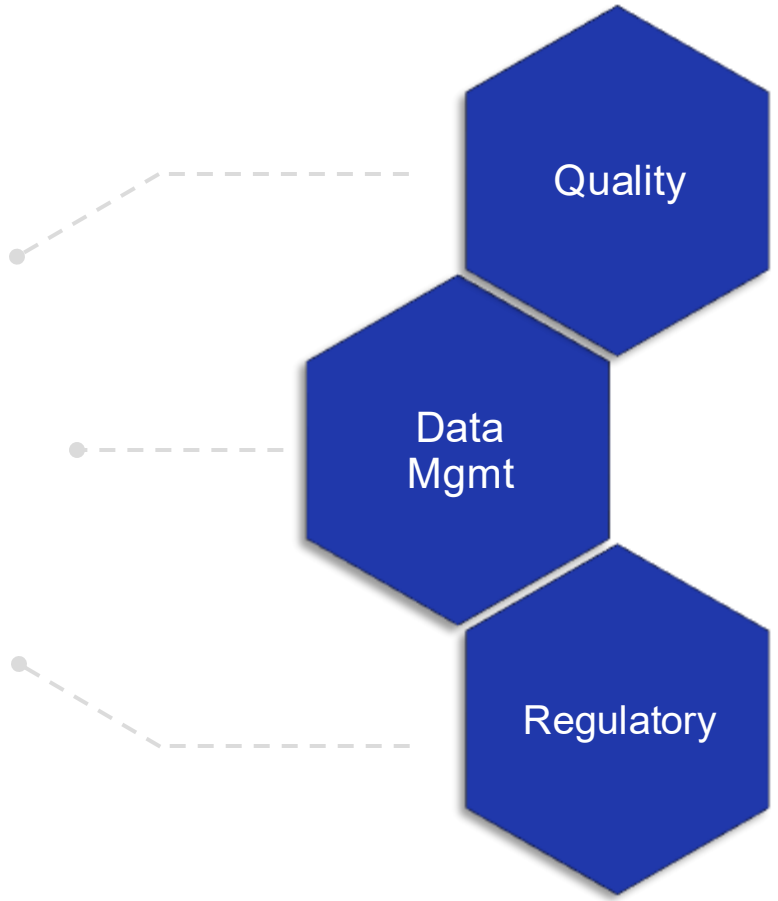
- An efficient and repeatable process
- Integrated with current processes
- Site Friendly
- Cost Effective
- **Patient Safety**

Stakeholder Alignment

Internal Stakeholders

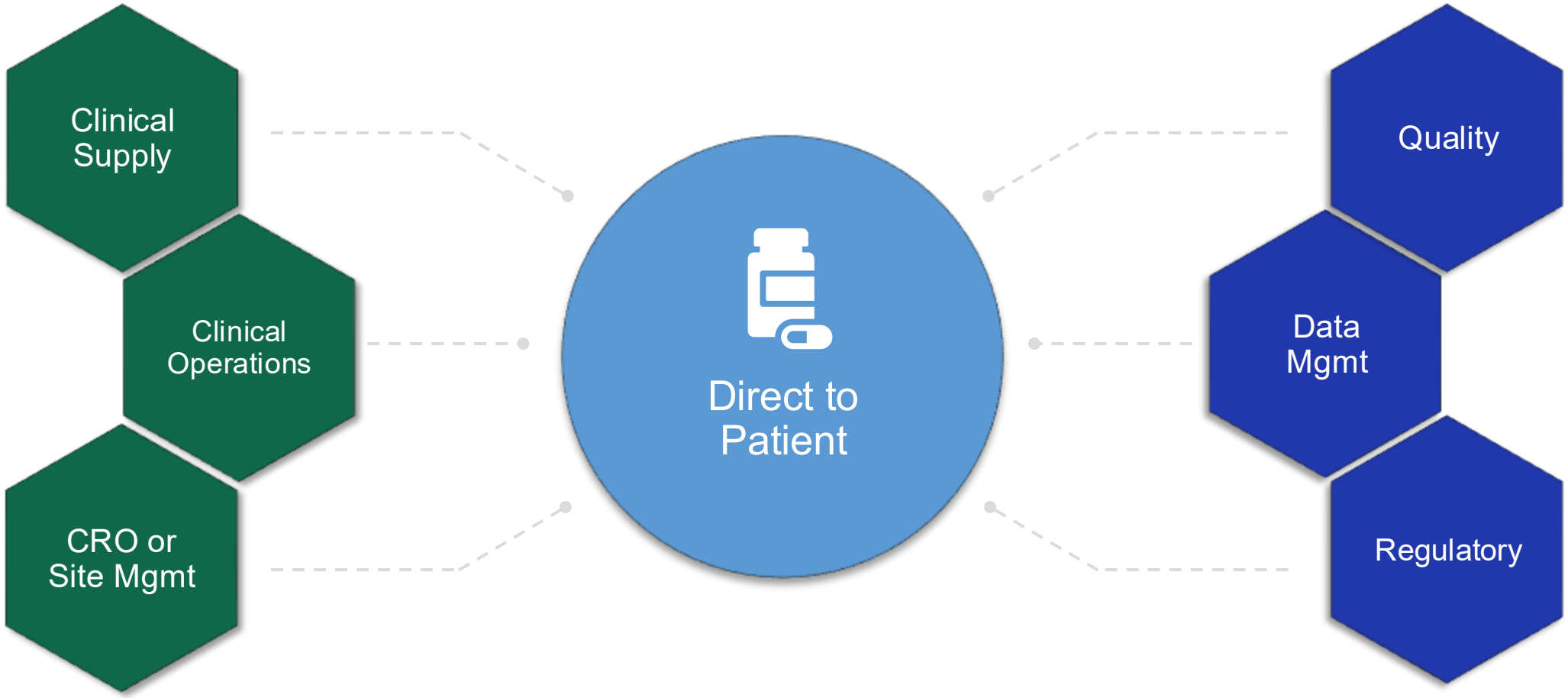
Goals

- Proper process governance, including approved processes
- Regulatory compliance in regions and countries
- Proper data privacy and data handling of PII and other pieces of data



Stakeholder Alignment

Internal Stakeholders: Ownership



Poll the Audience

Question: In your organization, who currently "owns" the DTP process strategy?

A. **Clinical Operations:** It's driven by the protocol and site management.

B. **Clinical Supply Chain:** It's viewed primarily as a logistics/distribution function.

C. **Innovation/DCT Team:** A dedicated specialized group handles it.

D. **It's Complicated:** Ownership is unclear or shared without a defined lead.

Sponsor Roadmap

Stakeholder Alignment

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Process Alignment

Process Design

Risk Assessment

Process Governance

DTP Decision Tree

Implementation

Process Alignment

Internal Process Alignment

Process Design

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Internal Process Alignment

Process Design

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Process Governance

Considerations

With stakeholders, create the DTP process:

- Order processing and delivery
- Clin ops considerations
  - Protocol considerations
- Site Management Considerations
  - Site and patient training
- What controls govern the process?

Outcome: high-level process map

Process Alignment

Internal Process Alignment

Questions to Ask

Identify potential risks in the designed process

- How can these risks be mitigated?
- What process steps need to be changed to mitigate risk?

How does this affect Patient Safety?

Process Alignment

Internal Process Alignment

Outcome of Process Alignment

Approved process to implement for studies

- Quality assessment
- Regulatory assessment

Blueprint on how to implement a DTP study

“DTP Decision Tree”

Process Alignment

DTP Decision Tree

DTP Decision Tree

Patient Safety

- Temperature Profile
- Administration Method
- Patient Profile
- Safety and Tolerability Factors

Trial Design

- Visit (Shipment) Schedule
- Kit Design
- Storage Space
- Investigator Oversight (Site Involvement)

Model Selection

- Site to Patient
- Pharmacy to Patient
- Depot to Patient
- Distribution Vendor Selection

Regulatory

- Countries Allowance for DTP
- Informed Consent

Poll the Audience

Question: What do you perceive as the single biggest barrier to implementing DTP in your trials?

A. **Site Resistance:** Sites fearing loss of oversight or revenue.

B. **Data Privacy:** Concerns over HIPAA/GDPR and handling patient data.

C. **Logistics/Cold Chain:** Managing temperature excursions and "last mile" delivery.

D. **Regulatory Uncertainty:** Navigating different approvals across countries.

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DTP Decision Tree

Implementation

Regulatory Considerations

Distribution Considerations

IRT Considerations

Implementation

DTP Decision Tree: Regulatory

European Medicines Agency (EMA)

- Decentralized Tasks outlined in the protocol
  - More detailed processes in related documents.
  - Example: Concurrent Regulatory Filing, Pharmacy Manual,
- Investigator maintains oversight of dosing
- DTP Model acceptance may differ from each member state

[Recommendation paper on Decentralized Elements in Clinical Trials - Version October 2025]

Food and Drug Administration (FDA)

- There is no difference between trials that include decentralized elements and those that do not.
- Ensure compliance with all relevant laws.
- Describe DCT/DTP operations in protocols.
- Additional training, coordination, and standard operating procedures may be necessary for decentralized elements

["Conducting Clinical Trials With Decentralized Elements" – Version September 2024]

Implementation

Distribution: Key Qualities of a Partner

- DTP experience with dedicated staff
- Global SOP's and adherence to GDP
- Blinding systems & processes
- Strong communication and escalation practices

Implementation

Distribution: Important Considerations

Trial Design

- **Product Type**
  - Controlled Substance
  - Dangerous Goods
- Blinding Requirements
- DTP/DFP
  - Returns
  - Labs

Logistics Requirements

- Country Profile
- Site Locations
- **Lanes**
  - Shipment types
  - Packaging placement plan
- **Monitoring and Packaging**

Process Alignment

- Communication
  - Home Health Nursing
- **Exception Management**
- Communication
  - Escalation
  - Contingency
- Process Agreement

Implementation

Distribution: Aligning Expectations

- Same day deliveries are not standard.
- Keep monitors and packaging standard, where possible.
- Transportation delays are inevitable; effective communication is key.
- Establish authorized contacts at the patient home for delivery.

Poll the Audience

Question: Regarding the "Last Mile" delivery to the patient's home, what worries you the most?

A. **Chain of Custody:** Ensuring the correct patient receives the drug (ID checks).

B. **Temperature Excursions:** Product stability sitting on a porch or with a courier.

C. **Patient Compliance:** Whether the patient stores/administers it correctly after receipt.

D. **Coordination:** The timing between courier delivery and home health nurse arrival.

E. **Patient Data Privacy Protection:** The collection and sharing of patient data

Implementation

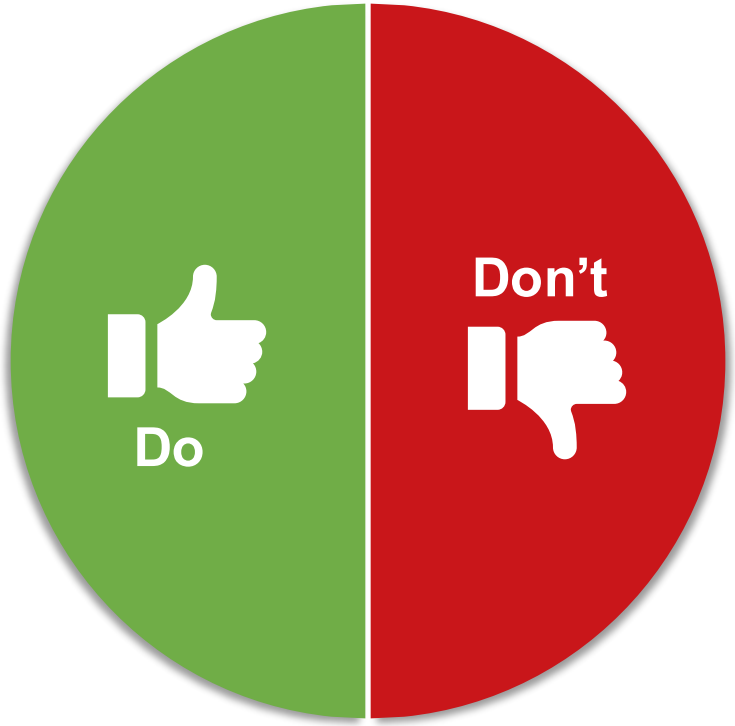
IRT Considerations: Flexibility in design

- Ability to opt in / opt out as a patient
- Enable / Disable at a site and depot level
- Ability to dynamically select DTP and Site visits
- Allow dynamic visit intervals- if necessary
- Allow unscheduled visits at site and/or patient home
- Allow dispensation from depot or pharmacy

Implementation

IRT: Data Privacy Do and Don't

- Comply with GDPR and HIPPA policies where required
- Secure and encrypt patient data appropriately
- Only collect essential information used in delivery
- Train all staff on safeguarding patient information



- Allow sponsors to access patient data
- Identify any study detail on shipper label
- Store patient details in TMF or uncontrolled systems
- Store data containing patient data longer than required

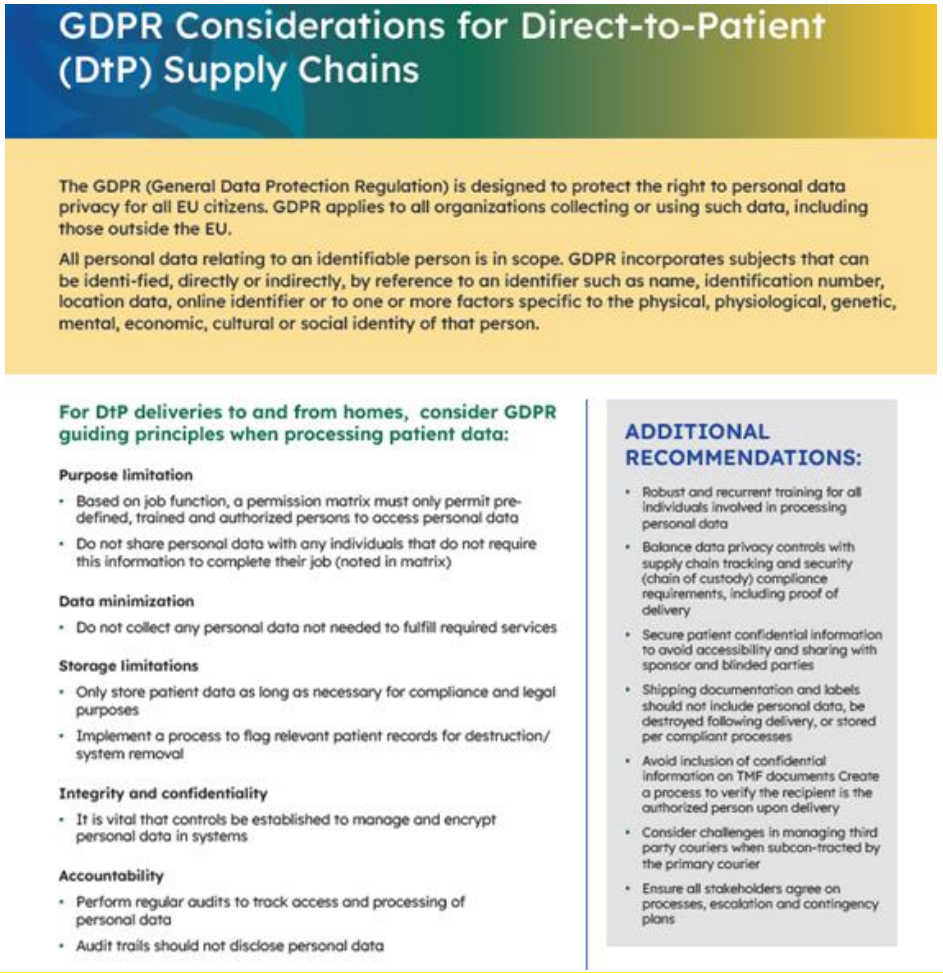
Implementation

IRT: Data Privacy – More information

GCSG article: GDPR Considerations for DTP Supply Chains

Review HIPPA and GDPR Regulations

Country and US state specific laws



GDPR Considerations for Direct-to-Patient (DtP) Supply Chains

The GDPR (General Data Protection Regulation) is designed to protect the right to personal data privacy for all EU citizens. GDPR applies to all organizations collecting or using such data, including those outside the EU.

All personal data relating to an identifiable person is in scope. GDPR incorporates subjects that can be identi-fied, directly or indirectly, by reference to an identifier such as name, identification number, location data, online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person.

For DtP deliveries to and from homes, consider GDPR guiding principles when processing patient data:

Purpose limitation

- Based on job function, a permission matrix must only permit pre-defined, trained and authorized persons to access personal data
- Do not share personal data with any individuals that do not require this information to complete their job (noted in matrix)

Data minimization

- Do not collect any personal data not needed to fulfill required services

Storage limitations

- Only store patient data as long as necessary for compliance and legal purposes
- Implement a process to flag relevant patient records for destruction/ system removal

Integrity and confidentiality

- It is vital that controls be established to manage and encrypt personal data in systems

Accountability

- Perform regular audits to track access and processing of personal data
- Audit trails should not disclose personal data

ADDITIONAL RECOMMENDATIONS:

- Robust and recurrent training for all individuals involved in processing personal data
- Balance data privacy controls with supply chain tracking and security (chain of custody) compliance requirements, including proof of delivery
- Secure patient confidential information to avoid accessibility and sharing with sponsor and blinded parties
- Shipping documentation and labels should not include personal data, be destroyed following delivery, or stored per compliant processes
- Avoid inclusion of confidential information on TMF documents Create a process to verify the recipient is the authorized person upon delivery
- Consider challenges in managing third party couriers when subcon-tracted by the primary courier
- Ensure all stakeholders agree on processes, escalation and contingency plans

Summary: DTP Sponsor Roadmap

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Thank you!
Questions?
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