Direct to Patient: Strategies, Processes & Lessons Learned

Sponsor’s Perspective
Patient Centricity
The DTP definition

*Delivery of clinical trial materials from an investigator site, pharmacy, or depot directly to a patient’s home.*

Reasons to consider Direct To Patient

**Geography**
- Patient remote from clinical sites
- Rural locations
- Delivery to alternate locations if patient is travelling

**Patient demographics**
- Health status / mobility of the patient
- Children and elderly
- Rare diseases

**Type of drug**
- Temperature Sensitive products
- Self administration vs. coordination with a nursing network
- High frequency of administration/long study trial duration

**Drug storage conditions**
- Temperature sensitivity
- Frequency of supply replenishment

**Cost**
- Patient visit / Investigator / Travel fees reduced or eliminated
- Higher retention and lower drop-outs due to ease of use
DTP process implementation timeline

2014
Presentation of the process to top management

2015
- Audit of the preferred carrier for this process
- Writing of quality documents, “Direct to patient process”
- Training of local monitoring teams

2016
- Amendment of Protocol templates
- Implementation of the first DTP shipments on a pilot study

Difficulties During Implementation

IS
Data Security
Sensitive data and encryption

Legal
Specific Contract Needed (MSA)

Compliance
Patient Confidentiality
Implementation Solutions

**IS Data Security**
- Use of cloud-based IT solution

**Legal Specific Contract**
- Implementation of a specific DTP MSA / Work Order template

**Compliance Patient Confidentiality**
- Amendment of protocol templates, informed consent, etc.
- Declaration made to appropriate authorities (Health authorities, Ethics Committees, National Commission on Informatics and Liberty, etc.)
- Dependent on country-specific data protection / data privacy regulations

Internal Survey on DTP: Summary

- **February 2017 Internal survey launched within R&D:**
  - Clinical
  - Project management
  - Clinical Supply Chain Operations
  - Procurement

- **196 survey participants**

- **Objective:** To obtain thoughts and feedback on protocol design and patient centricity
Internal Survey on DTP (1/4)

Should DTP be linked to specific studies / therapeutic areas (e.g. rare disease)?

- Yes: 50 responses
- No: 116 responses

Internal Survey on DTP (2/4)

Would a DTP option enabling enrolment of the “Working Sick” be an advantage for your study? “Working Sick” is defined as a study eligible subject that cannot be enrolled as a result of required treatment / site visits conflicting with work schedules.

- Yes: 84 responses
- No: 82 responses
Internal Survey on DTP (3/4)

Would you consider a DTP option for your study(s)?

- Yes: 60%
- No: 40%
- N/A: 0%

195 responses

Internal Survey on DTP (4/4)

How much added value would a DTP option offer to your studies?

- Significant: 30%
- Some: 60%
- Limited: 10%

136 responses
Sponsor Conclusions on Patient Centricity

• More and more data provided through connected devices -> Digitalization
• Less and less trips of patients to sites -> Direct To Patients solution
  • In all therapeutic areas and for medical emergencies

Logistics provider perspective

The Evolution of Direct to Patient
Why is Collaboration so Essential?

Opportunities

- Span across many therapeutic/treatment areas
- Rare diseases (limited patients)
- Complex project requirements
- Patients that are:
  - Chronically ill
  - Remotely located
  - Lack physical mobility
  - Pediatric/Geriatric
- Medications with the following properties:
  - High value
  - Frequent dosage
  - Temperature controlled
  - Personalized/orphan drugs
  - Require administering by a healthcare professional
- Variety is more than expected
DTP Distribution Models

- **Product**
  - Manufacturer

- **Packaging**
  - Centralized Packaging / Storage
  - US / EU

- **Regional**
  - In-Country / EU Depot

- **Local**
  - Site pharmacy (multiple)

- **Subject**
  - Patient Residence (nurse / patient)

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DTP Scope of Services Overview

**Services**
- Drug distribution (DTP)
- Kit / supplies deliveries (DTP)
- Specimen collections (DFP)
- Temperature control
  - Packaging
  - Monitors
- Returns / Accountability
- Investigational & Commercial

**Requirements / Challenges**
- Project setup / collaboration
- Standardized processes
- Country-specific requirements
- Data privacy / blinding
- Training (drivers, etc.)
- Adaptability
- Communication / Escalation
Activity Demographics

12,000+ shipments in FY17

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>Drug</td>
<td>62%</td>
</tr>
<tr>
<td>Specimens</td>
<td>32%</td>
</tr>
<tr>
<td>Kits / Devices</td>
<td>6%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Service</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTP (direct to)</td>
<td>58%</td>
</tr>
<tr>
<td>DFP (direct from)</td>
<td>42%</td>
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</tbody>
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Trends since 2012:
- 200+ different customers
- Activity in 30+ countries
- Over 40,000 shipments and 300 protocols worldwide
- Over 15% of activity is not related to clinical trials (e.g., commercial drug / expanded access, etc.)
- Increased focus on closing the supply chain loop (patient sample collections and returns)

Case Studies

**Orphan Drug**
- Quality Agreement requirement
- Issue resolution between sponsor, CRO, home care service, logistics provider and site pharmacy

**Life Saving Program**
- Commercial Product
- 24x7 On-Demand Dedicated Delivery
Innovations / Adjacent Services

- Clinical home care
- Virtual sites / trials / Site-less trials
- Temperature controlled packaging
- GPS / GSM / BLE (monitoring temperatures / location)
- In-home storage
- Returns

Trends & Lessons Learned

- Sustained increase in demand for DTP services
- Successful partnerships start with discussing and documenting study / project requirements
- Collaboration between all parties is crucial to the patient experience
- Service complexity can be significant and challenging (training is essential)
- Retaining patient confidentiality is paramount
- Standard processes are key, service flexibility is also essential
- Requires continuous improvement
- Lack of execution brings potentially high cost of failure
- DTP is expanding access to cutting edge medications to more patients