Practical and Legal aspects of patient-centric logistics in Clinical Trials

Kyiv, 9-Oct-2020
AGENDA:

1. Briefing on the matter;
2. Patient-centric focus;
3. Full cycle solutions;
4. Regulatory background of Patient-Centric logistics & Direct to Patient deliveries in Ukraine;
5. Guidelines and Direct to Patient Delivery process flow in terms of COVID-19.
BRIEFING ON THE MATTER:

- Clinical Trials market expected to reach USD 69.9 bn by 2027\(^1\)

- Number of complex clinical trials: Phase III dominated with a revenue share of 53.0% in 2019\(^1\)

- The drug development industry is expected to face a host of new challenges as it adapts to the digital era\(^2\)

- COVID-19 placed a tremendous strain on the clinical research enterprise\(^3\)

- Clinical trial stakeholders weigh in on the major shifts away from the traditional site-based model\(^4\).

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No standard definition of the Patient-Centricity

One of the first definitions: "Putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family."

(AstraZeneca at BMJ Innovations 2017)

SMO GROUP starts supporting patient-centric logistics in Ukraine in 2016 with patient transportation organization to clinical sites
FULL CYCLE SOLUTIONS

CLINICAL TRIAL LOGISTICS

- TAXI
- NURSE
- TRAVEL
- DIRECT TO PATIENT SHIPMENTS
- ACCOMODATION & NUTRITION
- REIMBURSEMENTS

Individual client approach
Personal Account Manager
24/7 Patient Support
Full coverage
Transparent reporting
Analytics
Clinical Trials Patient-Centric logistics **has no separate dedicated regulation in Ukraine**

As per ordinary business activities Patient-Centricity service fall under **regulated and complex area** of various of legislation

**COVID-19** influenced regulatory approach and raised opportunities to get experience & enhance utilization of patient-centricity service, especially in direct to patient deliveries
REGULATORY BACKGROUND

DEPOT-TO-PATIENT (DTP)

SITE-TO-PATIENT (STP)

HYBRID

USUAL CLIENT/SPONSOR REQUIREMENTS:

- Full coverage on regional level
- Just-in-Time car feeding
- Route tracking
- 24/7 patient support
- Compliance with personal data protection regulations
### Direct to Patient Key Regulation & Guidelines

<table>
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<tr>
<th>Common Terms</th>
<th>Specific Guidelines</th>
<th>COVID-19 related clarifications</th>
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<td>Licensing and differences to IMP and Non-IMP</td>
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<td>Order of the MOH Ukraine No. 690 dd 23/09/2009 “On approval of the Procedure for carrying out clinical testing of medicines...” Conditions on treatment of IMP and ancillaries in Clinical Trial</td>
<td>Order of the MOH Ukraine No. 95 dd 23/09/2009 “On approval of documents in quality...” GxP rules of distribution of IMP and ancillaries in Clinical Trials</td>
<td>SEC of MOH to EBA clarifications No. 16/40/K dd. 26/03/2020 “On possibilities to support emergency ensuring of continuous therapy...” List of measures to support direct deliveries to Patients in Clinical Trial</td>
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Risk assessment done by Sponsor on alternative means of delivery in terms of pp. 5.14.3 - 5.1.4.5 of local GCP

SOPs are to be developed following to the risk assessment to ensure safe and timely delivery

For deliveries desirable to use powers of a investigators/co-investigators but could be shipped through independent contracted distributor
COVID-19 DTP KEY GUIDELINES

- Staff involved in the delivery should undergo respective training considering the process

- An investigator should receive confirmation of all deliveries of an IMP

- Provision of an IMP to a third person (neighbor, etc.) is prohibited
COVID-19 DTP KEY GUIDELINES

- In exceptional cases re-distribute IMPs between Trial Sites in accordance with the GMP, Annex 13

- Recommendation to support the required IMPs\Non-IMPs backup in case of improper distribution

- An investigator remains in charge of the proper administration of an IMP by a study subject
COVID-19 DELIVERY SIMPLE FLOW

Sponsor

Investigator

DTP\STP shipments

Distributor