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].

Market potential!

Complexity!

Innovations!

COVID impact!

Shift to patient-centricity!

1 "Clinical Trials Market Size, Share & Trends Analysis Report by Phase (Phases I-IV), by Study Design (Interventional, Observational, Expanded Access), by Indication and Segment Forecasts, 2020 – 2027, May 2020.

2 "Press Release: New Tufts CSDD White Paper", Ken Getz, Research Professor and Deputy Director at Tufts CSDD, Jul 2020 .

3 "Impact of the COVID-19 pandemic on clinical research", Katherine R. Tuttle, Nature Reviews Nephrology, Aug 2020.

4 "COVID-Sparked Practices Driving New Patient-Centric Behaviors" Ann Neuer, MBA, is President of Medical deScriptions, LLC Jun,2020.

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

SMO GROUP EST.2004

Individual client approach

Personal Account Manager

24/7 Patient Support

Full coverage

Transparent reporting

Analytics

REGULATORY BACKGROUND

Clinical Trials Patient-Centric logistics **has no separate dedicated regulation in Ukraine**

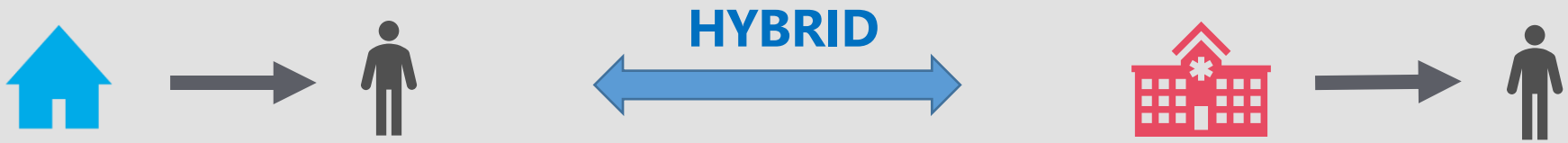
As per ordinary business activities Patient-Centricity service fall under **regulated and complex area** of various of legislation

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)



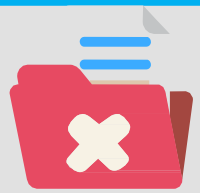
USUAL CLIENT\SPONSOR REQUIREMENTS:

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

Common Terms	Specific Guidelines	COVID-19 related clarifications
Law of Ukraine No. 123/96-BP dd 4/04/1996 *"On medicines"* Licensing and differences to IMP and Non-IMP	Cabinet of Ministers Decree No. 929 dd 30/11/2016 *"On approval of licensing conditions…"* Licensing conditions to support logistics of Non-IMP	SEC of MOH website guidelines dd. 17/03/2020 - 26/09/2020 *"Recommendations on clinical trials in quarantine…"* General suggestions to support deliveries in Clinical Trials
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	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	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

COVID-19 DTP KEY GUIDELINES

- 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

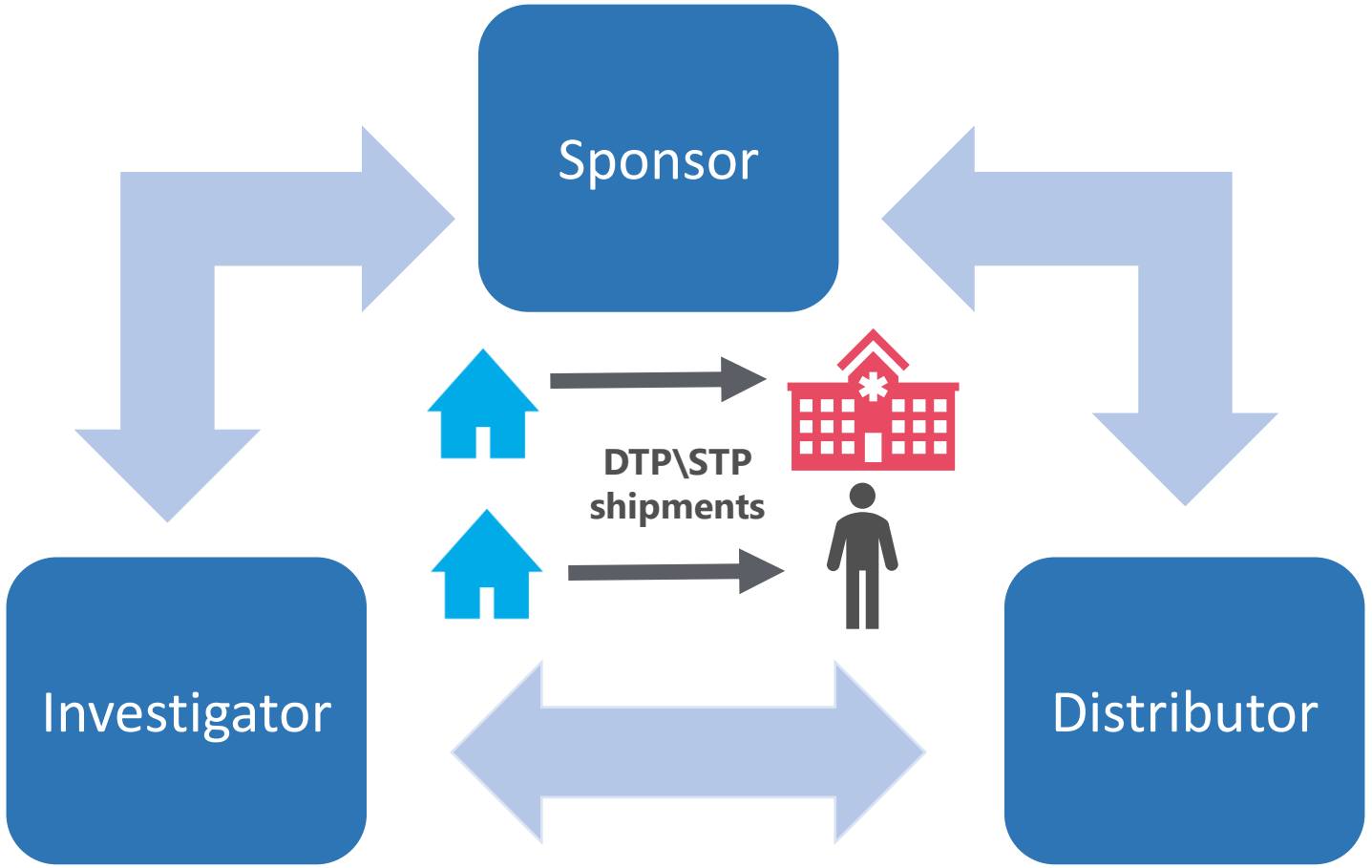
COVID-19 DTP KEY GUIDELINES

- ❑ 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



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