GLOBAL CLINICAL SUPPLIES GROUP

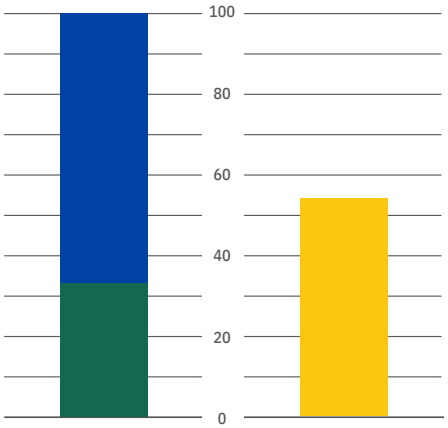
2022 GCSG Direct-to-Patient Survey

During the 2022 GCSG US conference in San Antonio, 65 attendees participated in the GSCG Direct-to-Patient Sub-Team's survey.

OF 65 SURVEY RESPONDENTS:

67% were individuals from pharmaceutical companies

33% were individuals from CROs, distribution providers, and other entities



54% had experience with DTP for either COVID-19 mitigation or planned protocol designs.

The preferred DTP delivery models were depot-to-patient (either local or central) or site-to-patient.

Major recommendations for future improvements included:

- ENHANCED TRACKING AND ACCOUNTABILITY SYSTEMS
- SITE-LEVEL SYSTEMS TO ENABLE DTP SHIPMENTS
- TEMPERATURE MONITORING SOLUTIONS

The DtP Sub-team is part of GCSG's Regulatory e-Team. The team's formation was announced in January 2022 with the following purpose: GCSG's DtP Team was assembled to educate our members on the rapid evolution and growth of Direct-to-Patient logistics services applied within clinical trials. The team is diverse in both clinical supplies/DtP experience and in global reach. Our objectives are focused on DtP and related supply chain solutions.

DtP Sub-team members (authors/contributors):

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- **Henk Dieteren,** Suvoda/The Clinical Supply Chain Management B.V.
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- **Lisa Falzone,** Bayer U.S.
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- **Lisa Killi,** Bellerophon
- **Keith Paulick,** Agios Pharmaceuticals
- **Michael Sweeney,** Independent Consultant
- **Terrence Walsh,** Walsh Pharma

The main reasons for considering DTP were:

- IMPROVING PATIENT RETENTION
- TRIAL CONTINGENCY PLANNING

The largest barriers to implementation were noted as:

- ADMINISTRATIVE BURDEN
- REGULATORY OR ETHICS COMMITTEE ACCEPTABILITY
- DISTRIBUTION CHALLENGES

A top challenge to standardization noted was:

- REGULATORY VARIABILITY