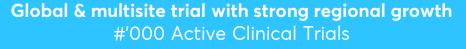
How the supply chain will need to adapt to support the growth of Decentralized Clinical Trials

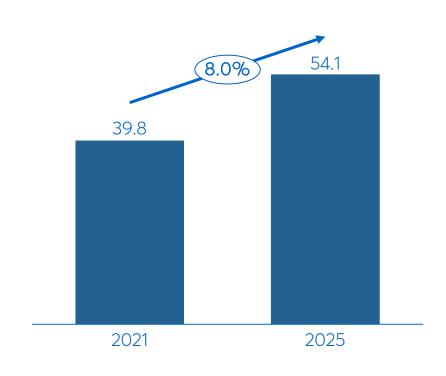
Claudia Berrón

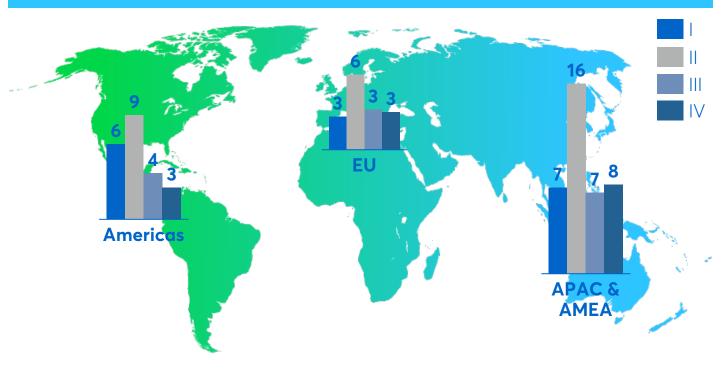


Continued growth of clinical trial landscape with increasing global reach







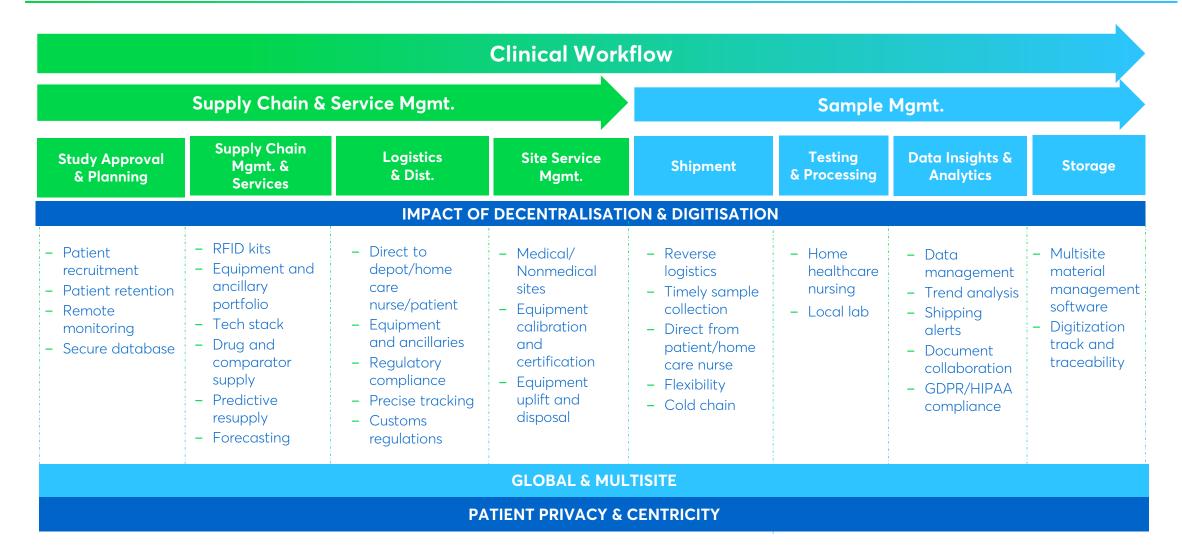


High-complexity, large-scope, global trials will continue to grow, with an estimated 20% of trials running in a decentralized structure – hybrid trials dominating active trials vs. fully virtual leading in post-market surveillance state IV.

Sources: Grand View Research 2021 / GlobalData 2/2022



Decentralization impacts every step of the clinical workflow





Decentralization and digitization go hand in hand



DECENTRALIZATION & DIGITIZATION



- Enrollment
- Engagement
- eConsent
- ePRO
- Retention



PRODUCTS

- Intuitive
- Medical
- Nonmedical
- Preloaded
- Integrated
- "Out of the box"



DATA

- Fundamental/validation
- Quality & integrity
- Compliance
- Multisite collection
- IoT
- eCOA
- Privacy



ANALYTICS



SUPPLY CHAIN

- Reduce risk/increase speed
- Real-time
- Predictive
- Al
- ML
- Safety monitoring
- Guided interventions

- Integration
- Visibility
- Real-time
- End-to-end



Decentralization & digitization leading to change in patient expectations

DECENTRALIZATION

Patient centricity



Supply chain



DIGITIZATION

Data



Products



Analytics



CONSUMERIZATION

- Simplicity
- Burden reduction
- Intuitive products
- Convenient participation
- Automatic compliance
- Guided activity
- Compelling engagement
- Improved flexibility
- First-class support

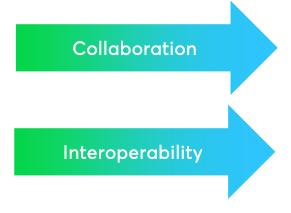
PATIENT EXPERIENCE



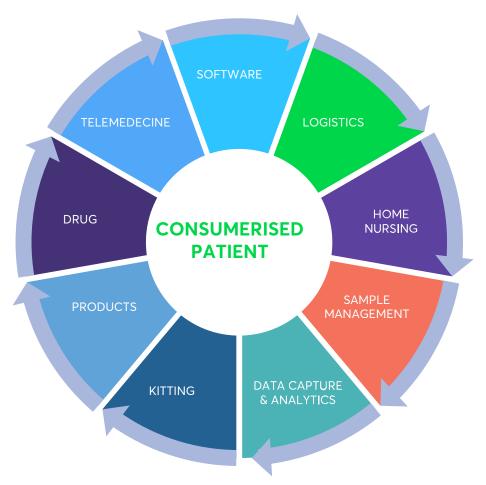
The supply chain challenge of consumerization

STAND-ALONE EXPERTS





COLLABORATIVE EXPERTISE





Collaborative ecosystem ultimately improving time to market

STAND-ALONE EXPERTS COLLABORATIVE EXPERTISE LOGISTICS SOFTWARE MEDICINE Collaboration HOME DRUG **CONSUMERISED** NURSING HOME SAMPLE **PATIENT** DRUG NURSING SAMPLE **Interoperability** DATA CAPTURE & **PRODUCTS** KITTING **ANALYTICS** DATA CAPTURE KITTING

BENEFITS TO THE SPONSOR

- Improved patient recruitment and retention
- Reduced cost
- Increased efficiencies
- Better patient representation
- Stronger data submissions
- Superior success rates



DRUG TO MARKET FASTER



Our experiences – in conclusion

	Decentralized					
Site-Based			Virtual			
Supply Chain Complexities						
7 DCT Diabetes, MS, Hepatitis B, COVID, Oncology	Phase I/II/III	c.240-800 Patients/Trial	c.2-3 Yr Duration	CRO & Sponsor	US/EUR/APAC Sites	

- Early, emergent signs of DCT adoption
- Adoption curve of virtual DCT solutions comfort with hybrid model
- Site and depot remain key supply chain entities
- New vendor partners entering supply chain particularly home healthcare nursing
- Patient data protection needs additional consideration throughout supply chain especially for direct-to-patient
- Not wholesale usage of digitized technology suite scales, CGM, BPM still significant alongside "consumer wearables"
- Openness to connect systems, but long road to achieve full connectivity



Our experiences – in conclusion

	Decentralized						
Site-Based			Virtual				
Supply Chain Complexities							
7 DCT Diabetes, MS, Hepatitis B, COVID, Oncology	Phase I/II/III	c.240-800 Patients/Trial	c.2-3 Yr Duration	CRO & Sponsor	US/EUR/APAC Sites		

- Not everyone set up to take full advantage of decentralized clinical trials
- Still some way to go toward fully virtual DCTs
- Vendors and CROs/sponsors need to collaborate to achieve a consumer patient experience
 & unlock all DCT benefits

