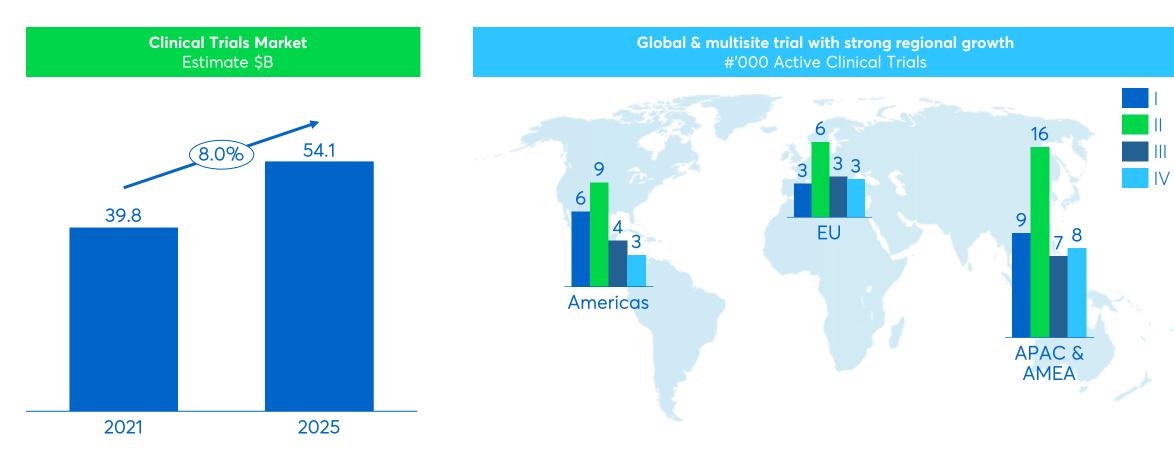
How will the supply chain need to adapt to support the growth of decentralized clinical trials?

Claudia Berron Senior Vice President, Clinical Services



Continued growth of clinical trial landscape with increasing global reach

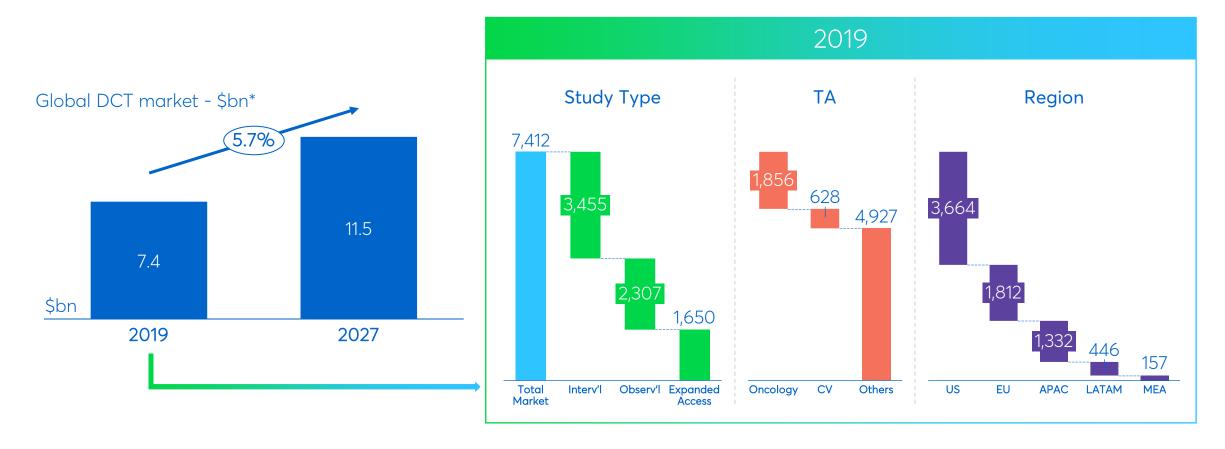


High-complexity, large-scope, global trials will continue to grow, with an estimated 20% of trials running in a decentralized structure – hybrid trials dominating active trials vs. fully virtual leading in post-market surveillance state IV.

Sources: Grand View Research 2021 / GlobalData



As DCT adoption increases, global DCT market set to continue growth



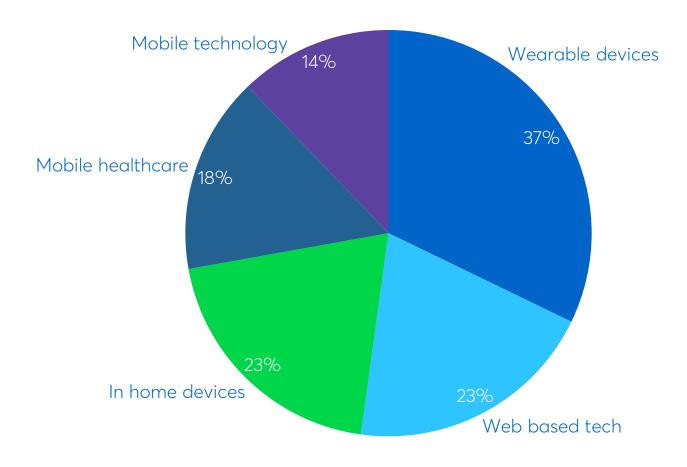
Adoption increases across different study types, with the US leading the way

*Source: Grand View Research - Virtual Clinical Trials Market (2016-2028)



Trials are considered DCT when they include specific products and services combined

COMPONENTS USED IN x% DCTs*



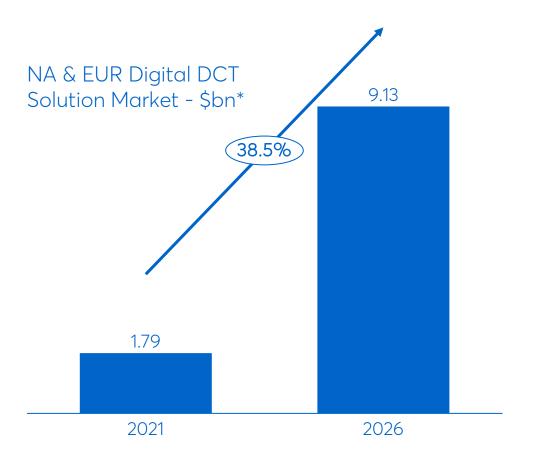
Wearable devices	Web based tech	In home devices	Mobile healthcare	Mobile tech
Activity tracker	Electronic data collection	Blood glucose monitor	Remote patient monitoring	Email
CGM	eCOA	Blood pressure monitor	Remote drug delivery	Text message
Heart monitor	eConsent	Electronic peak flow meter	Telemedicine	Webchat
	eDiary	Oximeter	Home nursing	Smart- phones
	ePRO			Tablets
	Questionnaire			

Health professional engagement away from traditional site is key component of a DCT – hybrid or virtual

*Source: Global Data, April 2022



Market for digital DCT solutions has boomed since start of pandemic, remaining dynamic, with rapid growth forecast



500+ vendors entering the supply chain with digital DCT solution in Europe and North America*

Investments in market grew by 114% in 2020 to reach \$750 million*

2021, \$710 million was raised in only first 8 months*

Players in market interact through both cooperation in partnerships, and competition for clients*

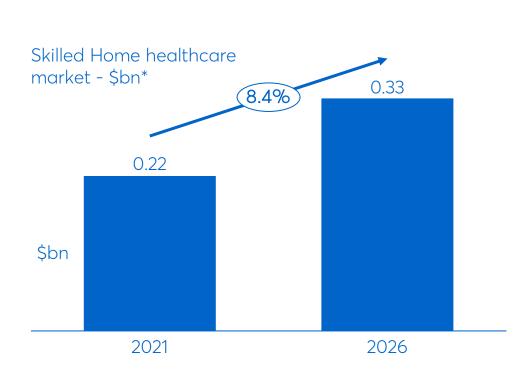
Simultaneously, market is quickly consolidating as key competitors acquire others*

*Cource:

Research 2 Guidance: The Digital Decentralised Clinical Trial Solutions Market-2018-2026



Growth of HHCN services market facilitates move away from central site, whilst enabling benefits of increased patient centricity



Patient recruitment 60%+ increase...
Patient retention 90%+...

...through decentralising and digitising site activities into patients' homes**



Source



^{*}Home Healthcare Market Estimates and Trend Analysis 2016-2027 –
Grand View Posearch

^{**} https://www.clinicalleader.com/doc/decentralized-trials-trends-technology-propelling-home-healthcare-services-0001)

Decentralization impacts every step of the clinical workflow

Clinical Workflow Supply Chain & Service Mgmt. Sample Mgmt. **Supply Chain Study Approval** Logistics **Site Service** Testing Data Insights & Mgmt. & **Shipment** Storage & Planning & Dist. Mgmt. & Processing **Analytics Services IMPACT OF DECENTRALISATION & DIGITISATION** - Direct to Patient - RFID kits Multisite - Nonmedical Reverse - Home - Data depot/home care recruitment healthcare logistics material Scannable labels sites management nurse/patient nursing Equipment - Timely sample management Patient retention - Trend analysis - Relevant software - Multiple calibration and collection equipment and - Local lab Remote Forecastina equipment certification Digitization ancillary portfolio monitoring Direct from - Predictive and ancillaries track and Equipment patient/home Completeness of Tech stack resupply - Regulatory traceability uplift and results care nurse - Drug and Shipping alerts compliance disposal Flexibility Secure database comparator Document - Precise tracking supply Coordination collaboration - Customs - Cold chain GDPR/HIPAA regulations compliance **GLOBAL & MULTISITE PATIENT PRIVACY & CENTRICITY**



Digitization and decentralization 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
- loT
- eCOA
- Privacy



ANALYTICS

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



SUPPLY CHAIN

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



Does decentralization x digitization = consumerization?

DECENTRALIZATION

Patient centricity



Supply chain





Data



Products



Analytics



CONSUMERIZATION

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

CONSUMER EXPERIENCE



Is the supply chain challenge of consumerization worth rising to?

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

BENEFITS TO THE SPONSOR

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



DRUG TO MARKET FASTER

80% clinical trials finish late due to patient recruitment challenges and drop out*

*Source: Global Data June 2021



Our experiences

				Decentralized	I			
Site-Based	Hybrid Hybrid				Virtual			
Supply Chain Complexities								
Diabetes, MS, Hepatitis B, COVID	Phase III	c.300 Patients/Trial	2-5 Yr Duration	CRO & Sponsor	US/EUR/APAC Sites			

Early, emergent signs of DCT adoption within our customers

Adoption curve of virtual DCT solutions not steep - comfort with hybrid model

Site and depot remain key supply chain entities

New vendor partners entering supply chain – particularly home healthcare nursing and digital DCT solutions

Patient data protection needs additional consideration throughout supply chain – especially for direct-to-patient

Willingness to connect systems, but long road to achieve interoperability

Not wholesale usage of digitized technology suite – scales, CGM, BPM still significant alongside "consumer wearables"



Our experiences

				Decentralized	I			
Site-Based	Hybrid			Virtual				
Supply Chain Complexities								
Diabetes, MS, Hepatitis B, COVID	Phase III	c.300 Patients/Trial	2-5 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 reach consumerized patient experience and unlock all DCT benefits

How can we work together to ensure this collaboration?





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