Decentralized Clinical Trials: Overview and Considerations

The difference is in the data.™

Our Presenter

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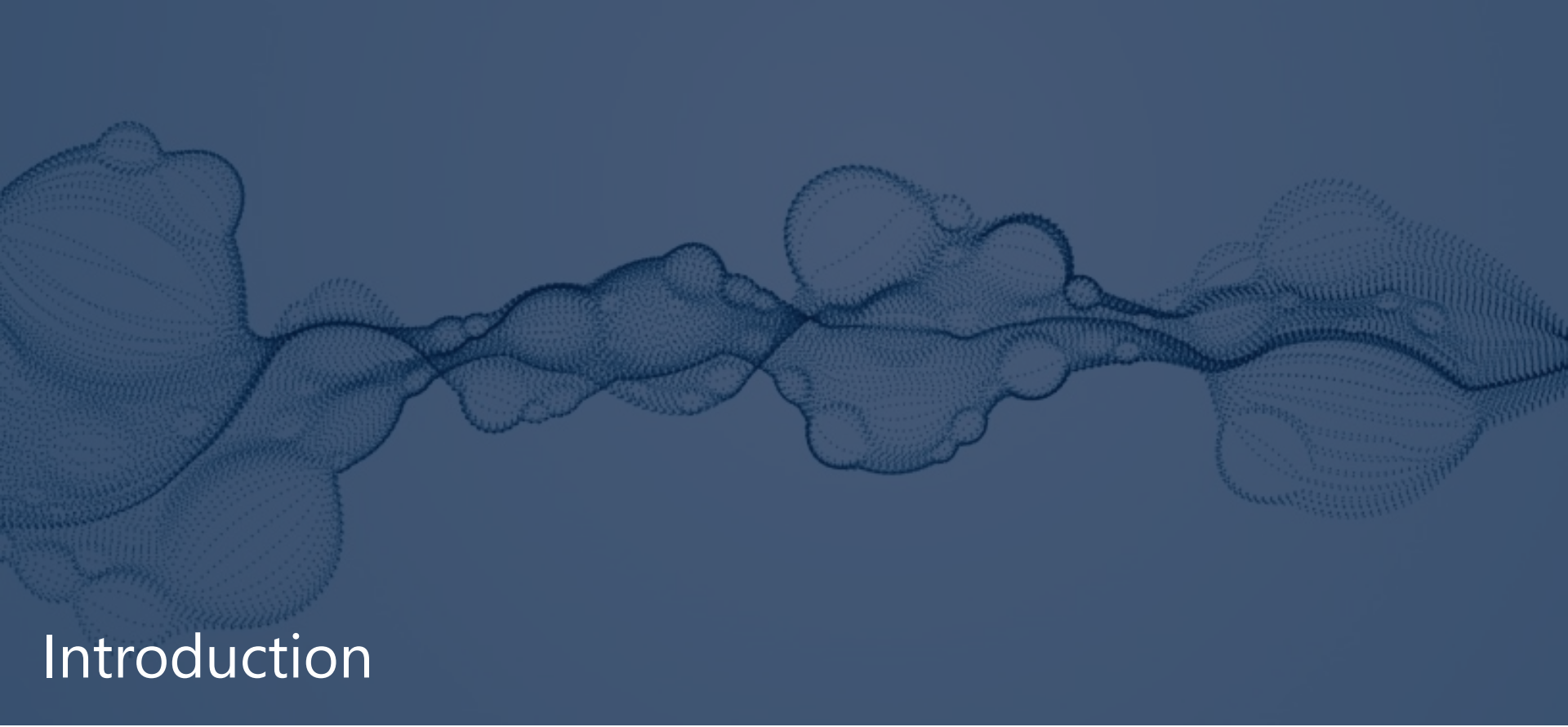
Agenda

- Introduction
- Decentralized Clinical Trial Methodologies
- Benefits of Hybrid/Full DCT Study Designs
- DCT Platform Capabilities
- Conclusion



Introduction

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Introduction

- **DCT** – Decentralized Clinical Trials. Trial designs that support less physical interaction with participants and more virtual support through various technology platforms
- **Telehealth** – Virtual consultations with health professionals allows long-distance patient and clinician contact, care, advice, reminders, education, intervention, monitoring, and remote admissions
- **ePRO/eCOA** – Electronic Patient Reported Outcomes/Electronic Clinical Outcome Assessments. Questionnaires that can be completed remotely by participants or practitioners through web/app-based technology
- **eConsent** – Electronic Informed Consent. Remote consent/assent signed by trial participants

Decentralized Clinical Trials

Hybrid

- Traditional site visits as well as remote telehealth/in-home visits
- Drug supply usually done at scheduled on-site visits
- Remote and on-site assessments

Full

- Remote telehealth visits with no on-site consultations
- Direct to patient drug supply
- Remote assessments through wearables and devices
- Remote sample collections

Decentralized Clinical Trial Methodologies

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Study Design Considerations

Just because you can, doesn't always mean you should!!

- Therapeutic Area and complexity of visit assessments
- Targeted age group and technology barriers
- Licensing requirements and validation timelines for remote applications
- Evaluate if DCT will enhance patient compliance, shorten timelines and decrease site burden
- Regulatory Requirements/Risk Assessment
- Infrastructure and regional challenges – Internet connectivity, power interruptions, high theft regions where device provisioning/replacement can be a concern
- Vendor selection and Validation for remote assessments

Planning and Other Considerations

The protocol, investigator plan and/or study document should provide detailed descriptions of the trial.

Other Pre-trial Considerations:

Contracts

Training

Data

Audits

Vendors

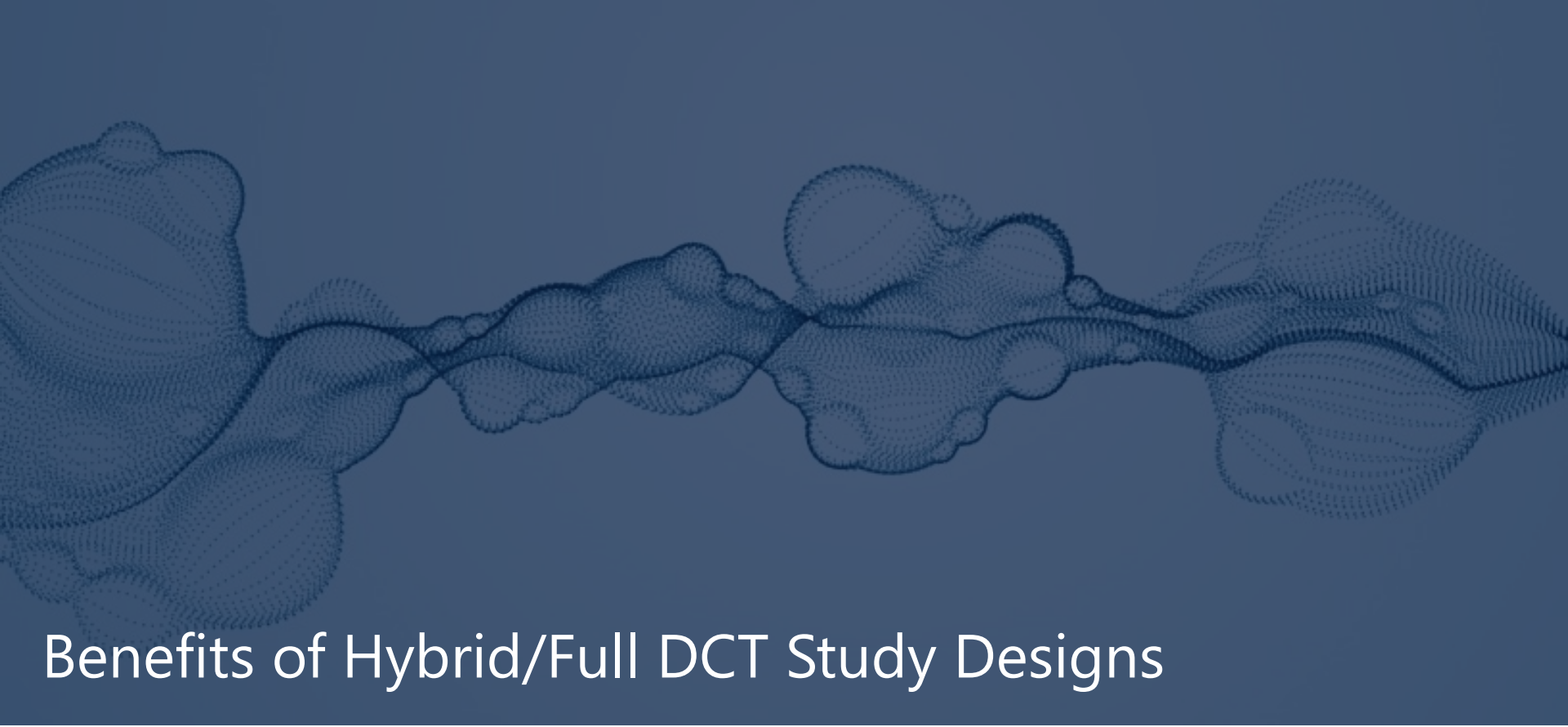
Risk Assessment

- Investigator and sponsor responsibilities do not change
- The risks to the quality and integrity of the study and the data that's being collected lie within the sponsor and investigator responsibilities
- Risk Assessment needs to be undertaken by the sponsor and particular risks must be identified

Dialogue/Early Engagement With Regulators

Early planning and designing of the trial, the sponsor should discuss the approach to be used with the Agencies:

- **MHRA:** Innovative Licensing & Access Pathway (ILAP) / Innovation, Scientific Advice meetings
- **FDA:** Pre IND (Pre-Investigational New Drug Application) meeting
- **HC:** Pre-application meeting with the Review Directorates, GCP requirements can be discussed with Compliance & Enforcement Unit



Benefits of Hybrid/Full DCT Study Designs

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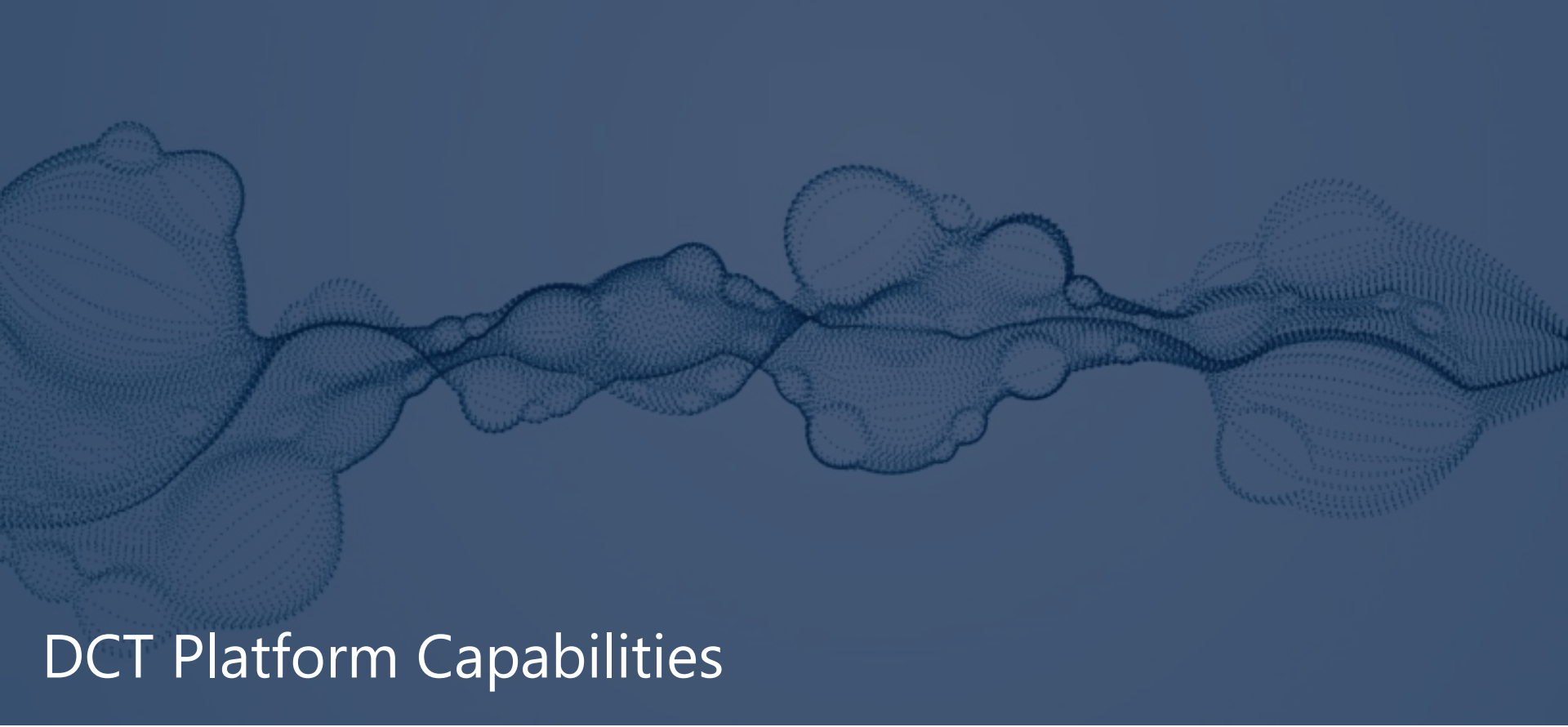
Benefits

- Patient Centric approach – ease of participation/better retention
- Enhanced recruitment – not limited to geographical locations, travel implications and time constraints.
- Diversity in study population – improves research quality
- Less travel and subsequent lower cost
- Reduced site burden



DCT Platform Capabilities

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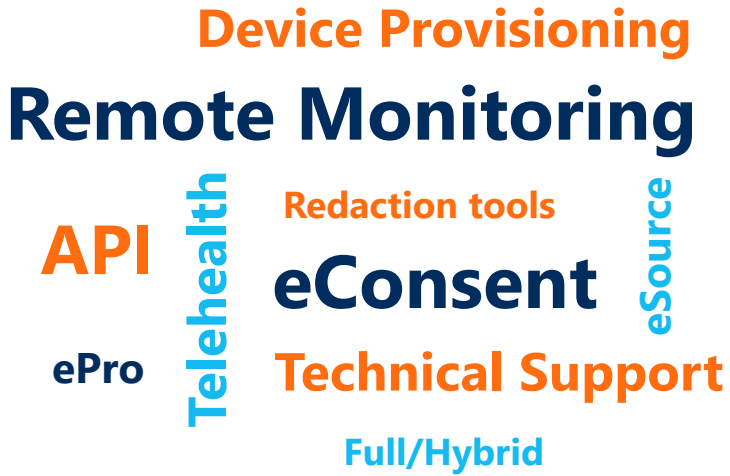
Various Platforms

Platform Considerations

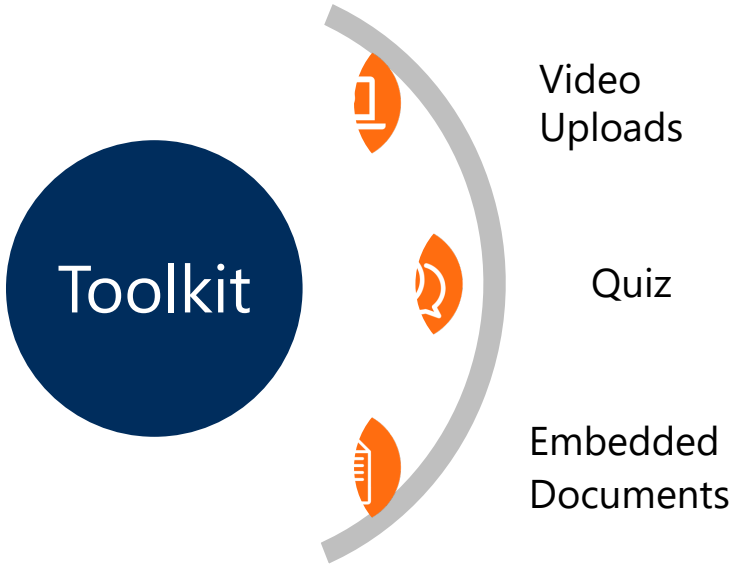
- Electronic Data Capturing platform options with DCT capabilities to suit the study design requirements
- Modular approach allows flexibility to only use and pay for what you need
- Technical support – System functionality as well as study specific requirements
- Integration capabilities to accommodate wearable and device data transfers etc.



eConsent

Allows patients to understand trial objectives while providing consent through multimedia technology onsite or remotely.

- Automated process – reduced consent errors
- Patient friendly – Easy to understand clinical trial information
- Comprehension Checks – enhanced compliance
- Consent Tracking
- Remote Monitoring



ePRO/eCOA

Standard Library
- Reduce build/UAT effort
- Expedited timelines

Licensing support
- Paper/Electronic, both?
- Requirements
- Costing

Validation
- Independent provider
- Internal/external

Web/app based
- BYO Device
- App for provisioned device

Scheduling
- Ensure questionnaires are not completed in advance etc.

PHI protection
- Rights and Role based

Translations
- Provide questionnaire in local language for enhanced comprehension
- Support multiple languages

Immediate data transfer on submit
- Real time data transfers
- Reduce site burden

Conclusion

- Decentralized Clinical Trials **compliment certain study designs** but **do not fit all Therapeutic Areas**
- Functionality requirements need to be considered when selecting the EDC/DCT platform – **Not a one size fits all**
- **Licensing and validation timeframes can play a big role** in DCT database design and release to production
- **Close collaboration** between Data Management and Clinical Operations is now more important than ever

Thank you!

Any questions?

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