Global Harmonization Center Clinical Trials Webinar Part 4:

Non-Traditional Trials & Data Governance: Implications of ICH E6(R3) Annex Concepts

Best Practice Data Governance in Decentralized Clinical Trials

Todd Rudo, M.D.

Chief Medical Officer, Clario



What is a Decentralized Clinical Trial (DCT)

Globally harmonized concept (FDA, EMA, PMDA, MFDS emerging alignment)

Health authority perspectives on DCTs:

A study the follows existing Good Clinical Practice (GCP) requirements, including participant protection, investigator responsibility, and data integrity, while incorporating some or all trial activities outside of a traditional clinical trial site.

Decentralized elements include:

- Telehealth visits with trial personnel
- In-home visits with remote trial personnel and investigator oversight
- Digital technologies to enable remote data capture



Regulatory expectations in DCTs

Focus on data integrity oversight, traceability and security

Same regulatory expectations

- Data Integrity
- Participant Privacy
- Secure Systems
- Auditability and Traceability
- Vendor oversight
- Risk-Based Monitoring
- Compliance with ICH E6(R2/R3) principals
- Align with local regulations (MFDS, PIPA)

Global Regulatory Expectations

- Sponsors maintain responsibility for oversight and data quality
- Use secure, auditable electronic data systems
- Digital technologies require appropriate validation and monitoring
- Maintain regulatory-ready documentation and traceability



Blood pressure monitoring

Different modalities must still produce comparable endpoints

In-Clinic BP Monitoring



- Scheduled Clinic Visits
- (Static timepoint)

Ambulatory BP Monitoring (**ABPM**)



- 24 hr. out of office
- (Day/night – circadian rhythm)
- Pre-defined hourly inflation schedule

Home BP Monitoring



- Remote extended monitoring period
- Pre-defined daily AM/PM assessment schedule



Key considerations for remote BP solutions

Scientific

- In what **setting** is this being collected?
- Do you need data **daily** or over a 24-48–hour period?
- Will a healthcare professional be involved?
- What is the **population**, and are there any specific considerations (e.g., pediatrics)?
- Which specific endpoints are you measuring?

Technology

- Is a scheduled **inflation plan** needed?
- Do you need **reminders**?
- How quickly does the data need to be back at the site?
- How familiar are staff members with the procedure?
- Based on the study length, are **accuracy checks** required?

Operational

- **Training**
  - Who needs to be trained?
  - In **what environment** will they be using the device?
- In which **countries/regions** are you entering?
- What is your timeline, and how to best fit your device deployment schedule into that?
- Can we **reuse devices**, or does this have to be one to one?

Key Benefits and Considerations for Remote BP Monitoring

- Supports remote BP assessment for efficacy, safety, and eligibility
- Enables virtual and longitudinal blood pressure monitoring
- Requires DCT-ready protocols, device workflows, and oversight
- Operational considerations include logistics, connectivity, and device management



Flexible ECG collection without compromising control

Multiple collection models, all with standards for data quality

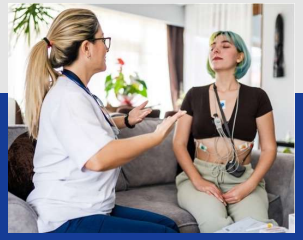
Site-base collection



- 12-lead ECG
- Continuous ECG

Gold standard collection

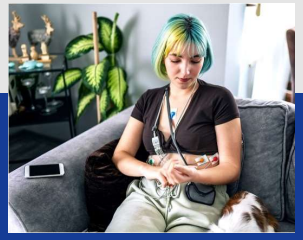
Home collection
(clinician supported)



- 12-lead ECG
- Continuous ECG
- Patch arrhythmia

Maintains site-level rigor

Home collection
(patient only)



- 6-lead ECG
- Remote capture devices

Patient-centric data collection



Home ECG: Flexible collection, centralized control

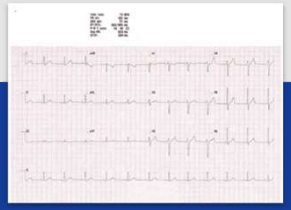
From nurse-led to patient-administered, data flows into a single, controlled system

Visiting nurse
(standardized equipment)



- Standardized device across all participants
- Full digital waveform capture
- Direct integration with Clario platform

Visiting nurse
(non-standardized equipment)



- Paper or local digital ECG
- Uploaded to centralized platform
- Converted for standardized review

Patient administered ECG



- Simple, guided device workflow
- Portable patient-friendly ECG monitoring
- Clinically validated cardiac insights



Patient-collected ECG: Clinical-grade data with central oversight

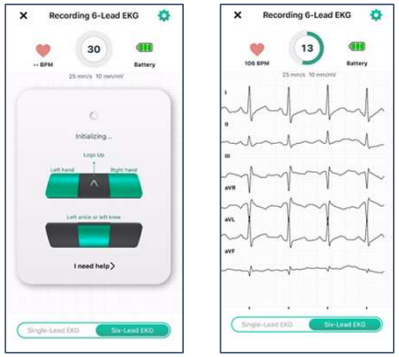
Purpose-built for clinical trials, not consumer monitoring

Capture



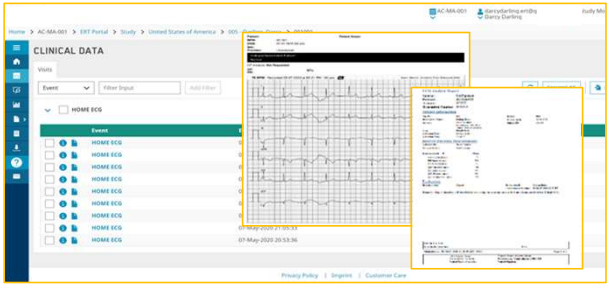
- Simple, guided 30-second ECG capture
- Designed for patient usability
- Bluetooth connection to app

Transmit



- ECG captured in app
- Real-time transmission via mobile network
- Available in platform within minutes

Central Review



- Patient managed via Clario portal
- Centralized data repository
- 100% cardiologist overread



Key ECG considerations for remote solutions

Cardiac Safety - ECGs

Scientific considerations

- What is the **population**, and are there any specific considerations (e.g., pediatrics)?
- Should you use a 6-lead or 12-lead device?
- Will **site visits** also be involved?
- Are you looking for **replicates or single** ECGs?

Operational considerations

- Is there a **traveling nurse** or healthcare professional?
- Does the traveling nurse already have a remote ECG solution?
- What is your **timeline** and **country** breakdown, and how do we best fit customs and your device deployment schedule into that?

Technology considerations

- **How often** and for how long will the device be used?
- Will these assessments be taken on a **specific schedule** (when the participants will need a reminder), or will they be using it more as an event monitor?
- Will assessments occur in the participants' homes?
- In what **country** do the participants live?
- Are we providing the **cell phone** devices?
- What is the **duration** of the trial?

Risk Mitigation and Controls

- **Device approval gaps:** Only deploy devices approved or supported in target regions (including Korea)
- **Translation delays:** Localization planned and validated prior to study start
- **Lead limitations:** Device selection aligned with endpoint requirements



Home Spirometry: Clinical-grade data for regulatory submission

Remote collection with built-in coaching, validation, and real-time control

Clinical Standard

- Meets ATS/ERS spirometry standards
- Captures full, high-quality pulmonary endpoints
- Equivalent rigor to site-based testing

Patient Execution

- Guided workflows and training
- Real-time feedback on technique
- Remote clinician coaching
- Coaching reduces variability in data

Data flow and governance

- Automatic data transmission
- Real-time visibility and monitoring
- Alerts for missed/poor-quality tests
- Centralized expert review

Built-in data integrity controls

- Standardized testing protocols
- Near real-time quality checks
- Coaching and validation controls
- Centralized oversight and review

Guided patient behavior enables reliable, regulatory-grade endpoints

Home Spirometry: Virtual Coaching

Clinician-directed coaching improves spirometry data quality



The Process

- Participants are connected in-app with a trained clinician
- Clinicians coach the participant through the full spirometry maneuver
- Data is transmitted
- AI-driven assessment tools provide quality feedback

The Result:

Improved Data Quality

- Tests are performed properly to meet ATS/ERS standards
- Improperly performed tests can be repeated with clinician coaching as needed

Clinician coaching and AI-driven feedback improve spirometry data quality



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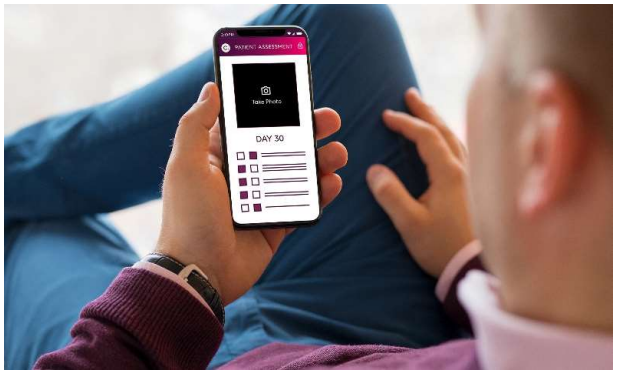
eCOA: Structured, Attributable, and Audit-Ready Data

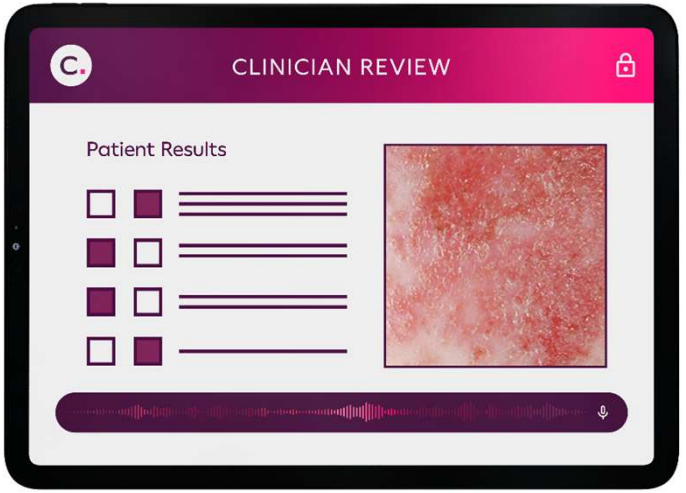
Enhances and augments clinical trial data

ePRO

+

Photo capture





- Time-stamped and attributable data capture
- Integrated photo + ePRO collection on a single device
- Supports endpoint completeness and verification

All entries are captured within a validated system with full audit trail and traceability

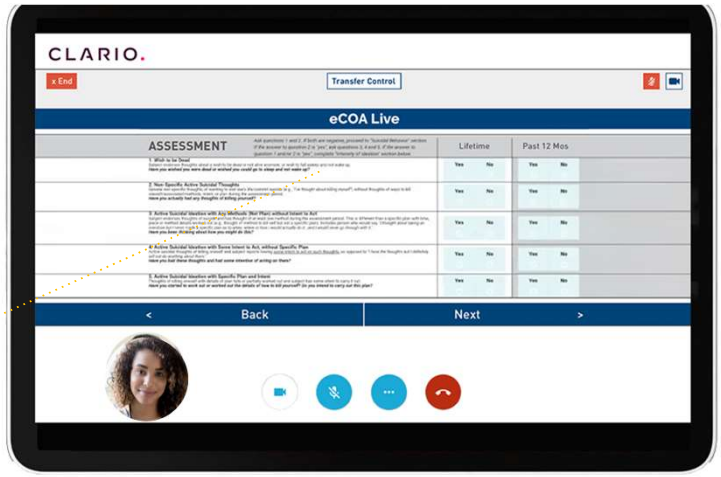


eCOA live: Hybrid data collection with bias control



Clinician provides support at site

Transfer Control



Clinician and patient 'pass' control of the assessment virtually



Patient completes site assessments electronically, in complete privacy at home

- Maintains assessor interaction when required
- Enables independent patient responses
- Reduces risk of reporting bias

Supports protocol-defined administration and data integrity requirements



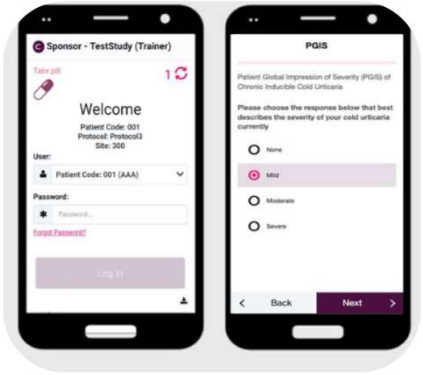
eCOA: Compliance and data quality by design

Designing patient experience to ensure complete, accurate, and unbiased data

Guided Workflows

Compliance by design

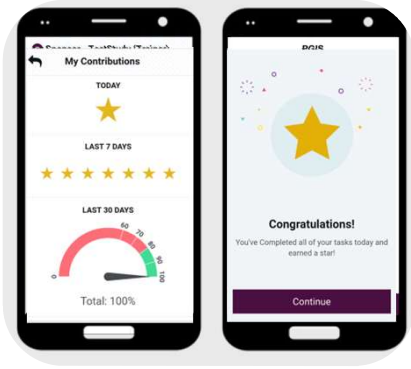
- Simple, guided assessments reduce patient error
- Built-in reminders ensure timely completion



Engagement tools

Patient Connect

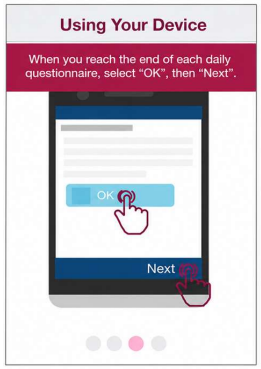
- Motivational tools drive adherence
- Real-time visibility into compliance



Training and Support

Interactive training modules

- Interactive training improves consistency
- Clear guidance increases compliance





Key Takeaways

- Decentralized trials **maintain the same regulatory standards** as traditional site-based studies
- All data **collection methods are validated** to ensure endpoint equivalence and reliability
- Centralized systems **provide full traceability, auditability, and a single source of truth**
- Built-in controls (protocol design, workflows, and monitoring) **ensure data integrity at all stages**
- Remote and hybrid models **enable high-quality, compliant data collection across diverse patient populations**
- Solutions are **aligned with ICH GCP** and adaptable to local regulatory requirements, including MFDS

