Clinical Trials Data

Clinical Trials Data Flow & Systems

Data Sources

- 🏫 Trial Sites
- 🧪 Central Labs
- 📱 ePRO/Wearables
- 📋 EHR Systems

EDC System
(Electronic Data Capture)

- eCRF Forms
- Edit Checks & Validation
- Audit Trail (21 CFR Part 11)

CDISC Standards

- CDASH — Data Collection
- SDTM — Tabulation Model
- ADaM — Analysis Datasets

Outputs

- DSMB Reports — Safety Monitoring
- Statistical Analysis — SAS, R, Python
- Regulatory Submit — FDA, EMA
- Publications — Clinical Trial Results

Future: EHR-EDC via FHIR

Real-time data collection → Standardized formats → Regulatory compliance → Evidence generation
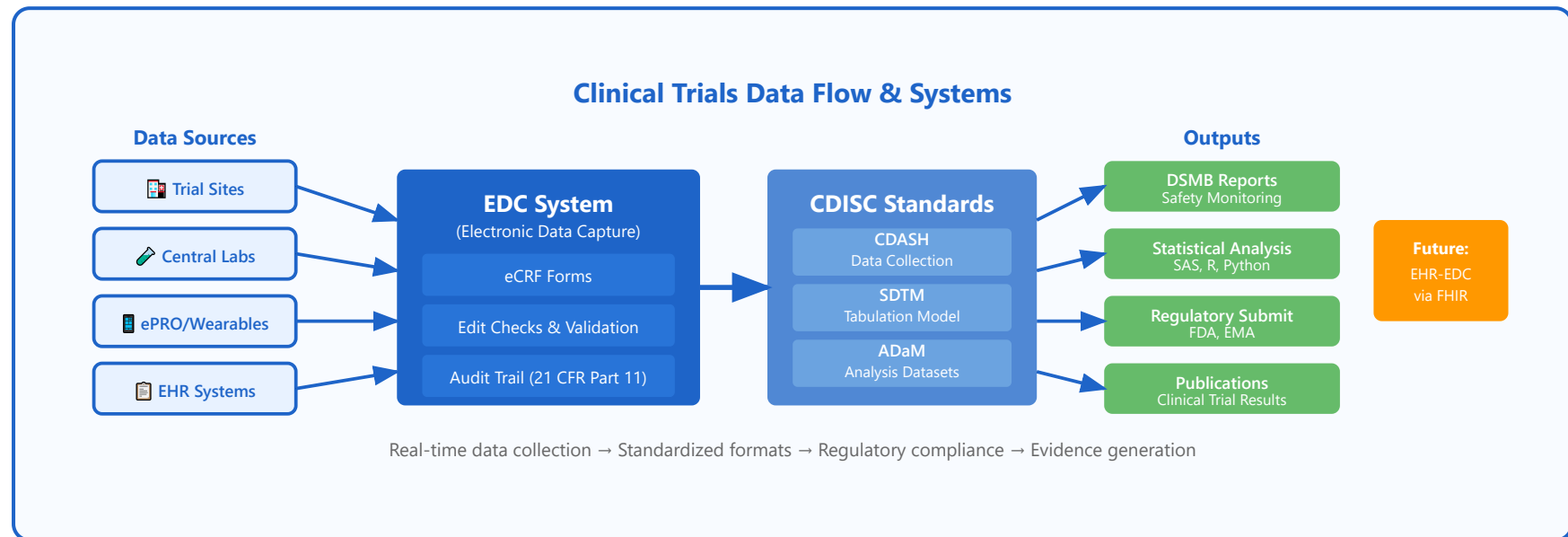
💻 EDC Systems

- Electronic Data Capture
- eCRFs (case report forms)
- Real-time data validation
- Query management
- 21 CFR Part 11 compliance

📊 CDISC Standards

- CDASH: Collection standards
- SDTM: Tabulation model
- ADaM: Analysis datasets
- Define-XML: Metadata
- Regulatory submissions

📈 Data Monitoring

- DSMB: Safety monitoring
- Interim analyses
- Stopping rules
- Adverse event tracking
- Risk-based monitoring

🔗 EHR Integration

- Direct data transfer
- Automated eligibility screening
- FHIR for interoperability
- Reduces duplicate entry
- Real-world data linkage