Ensuring Data Quality in Decentralized Clinical Trials: A Strategic Approach

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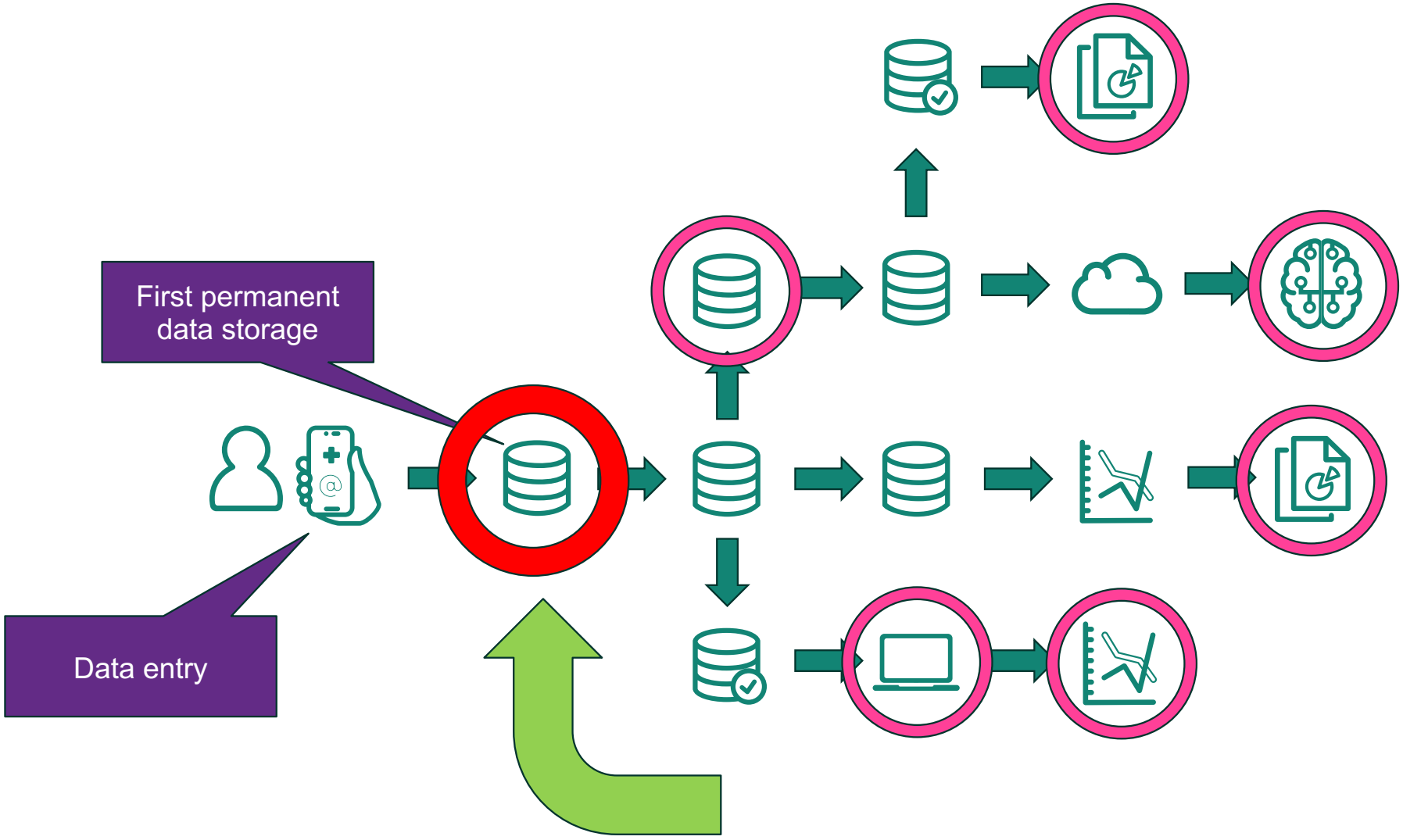
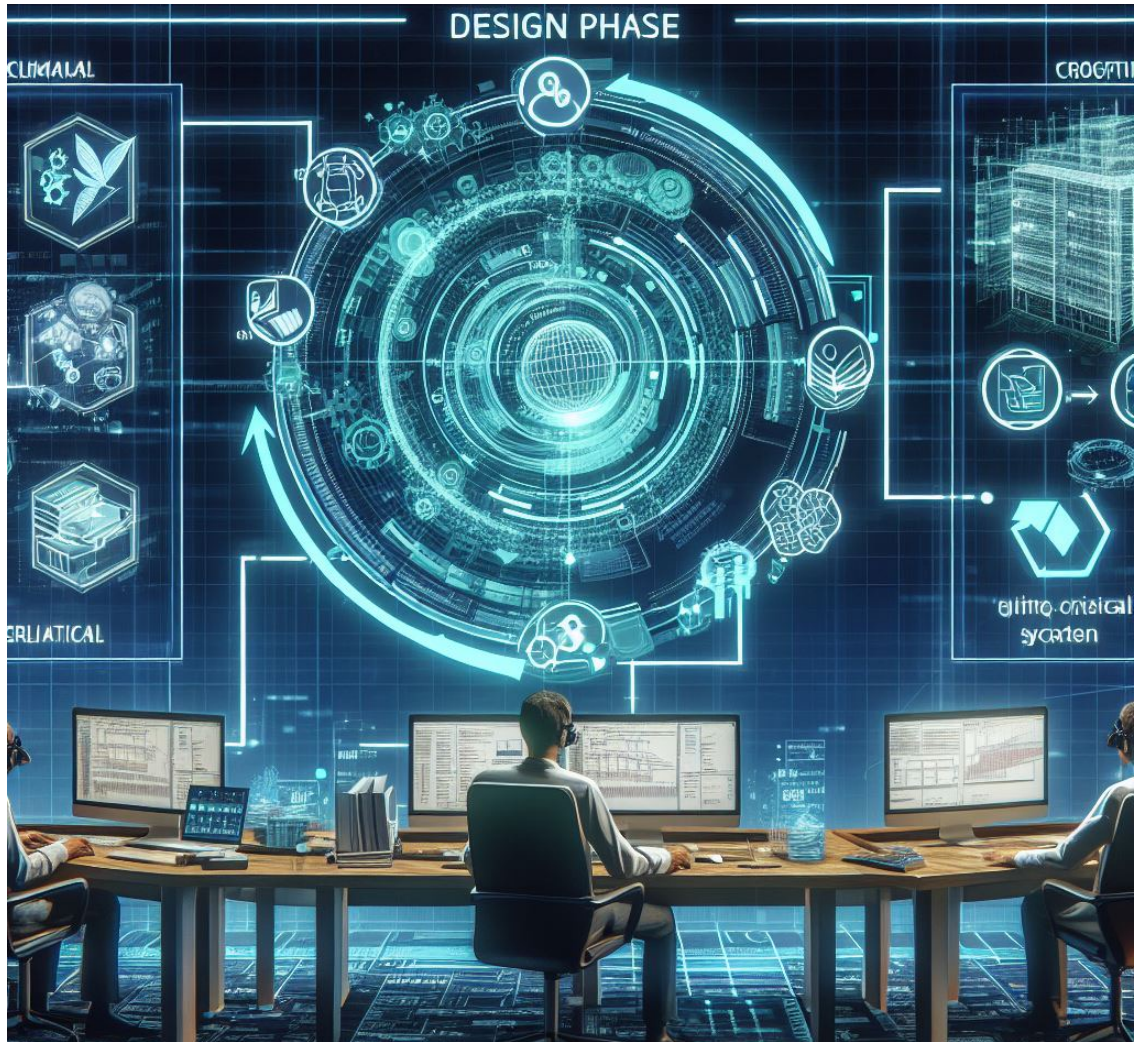
Decentralized Clinical Trials

DCT data flow



Decentralized clinical trials

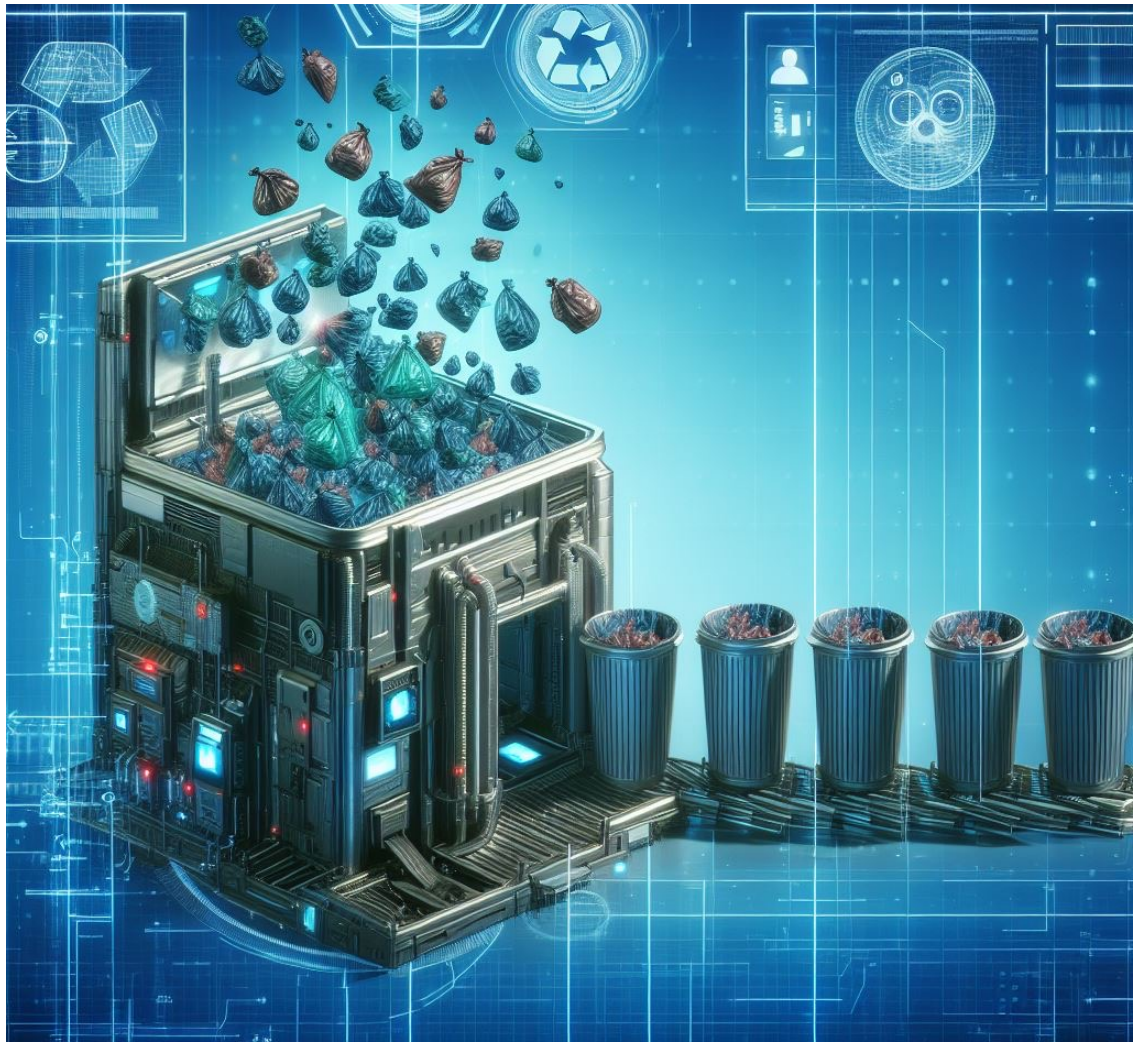
- Good design is a key to success
  - Protocol design
  - System design
  - Data flow design
  - Study configuration design
  - Built-in end-to-end data integrity assurance
  - Built-in risk management throughout the study lifecycle



Design your study well before you launch it!

Scientific principle

Data quality: garbage in – garbage out

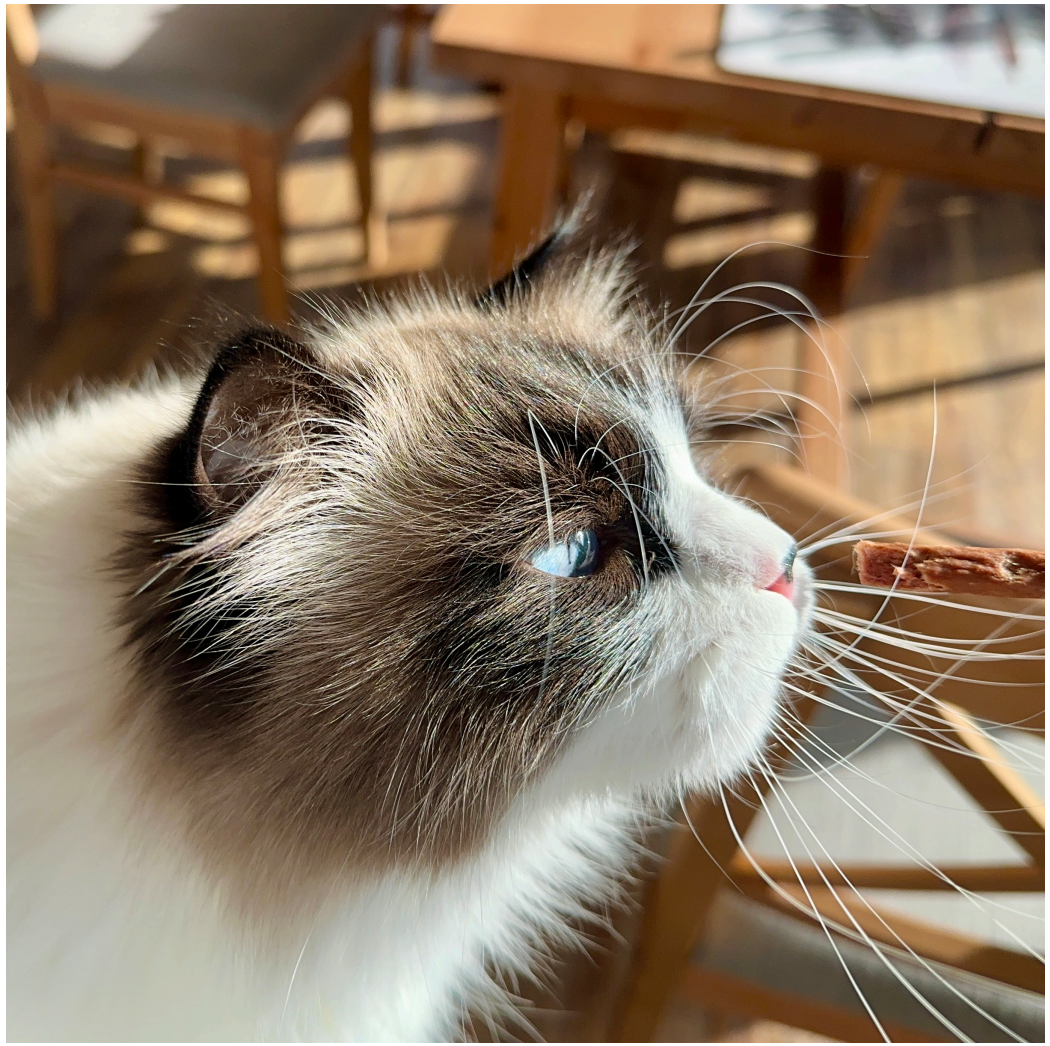


– The principle of garbage in, garbage out (GIGO) means that the quality of the output of a system depends on the quality of the input.

Do not let bad data into your system

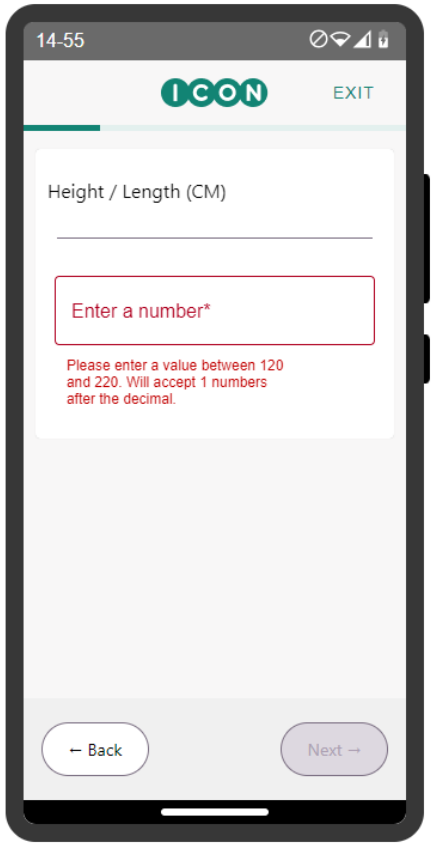
- Carefully consider which data must be collected and for what purpose
- Ensure that data collection forms are clear and not ambiguous
- Intuitive user interface helps data collection
- Ensure that training, user support and technical aids are available
- Design and implement data edit checks / data validation rules

Learning from the nature: sniff test



Data validation

- Data validation
  - Hard checks
    - An error message is shown, and the system would not allow a user to advance until the error is corrected
  - Soft checks
    - An error message is shown allowing a user to either correct the error or continue as is



Data validation

- Level 0: completeness validation (required fields)
- Level 1: syntax validation (data type, format)
- Level 2: simple range checks
- Level 3: consistency validation [simple correlation between the fields on the same form (if A>0 than B<10)]
- Level 4: relation of a field value for other study parameters (if more than 3 weeks after randomization, the value should be above X)
- Level 5: relation to previously collected data for the same subject (same patient statistical outliers)
- Level 6: relation to other patients in the study (statistical outliers)
- Level 7: relation to real world evidence

Case study

Case study: eDiary body temperature measurement

- Vaccine study (multi-center international study)
- eDiary on a smartphone
  - Subjects respond to questionnaires at multiple timepoints throughout the study
  - Critical timepoints: several days following vaccinations
  - One of the datapoints: body temperature following the vaccination (daily)
  - Database lock: approx. 9 months after the first vaccination
- Challenge: some datapoints were not valid and required clarification

Case study: eDiary body temperature measurement

- Patient reported value: 9.8°F (-12.3°C)
  - The value is obviously wrong
  - Value is outside of possible range for human body
- Assumption: data entry error
  - Intended value: 98°F (36.7°C)
- Issue identified almost 9 months after data collection

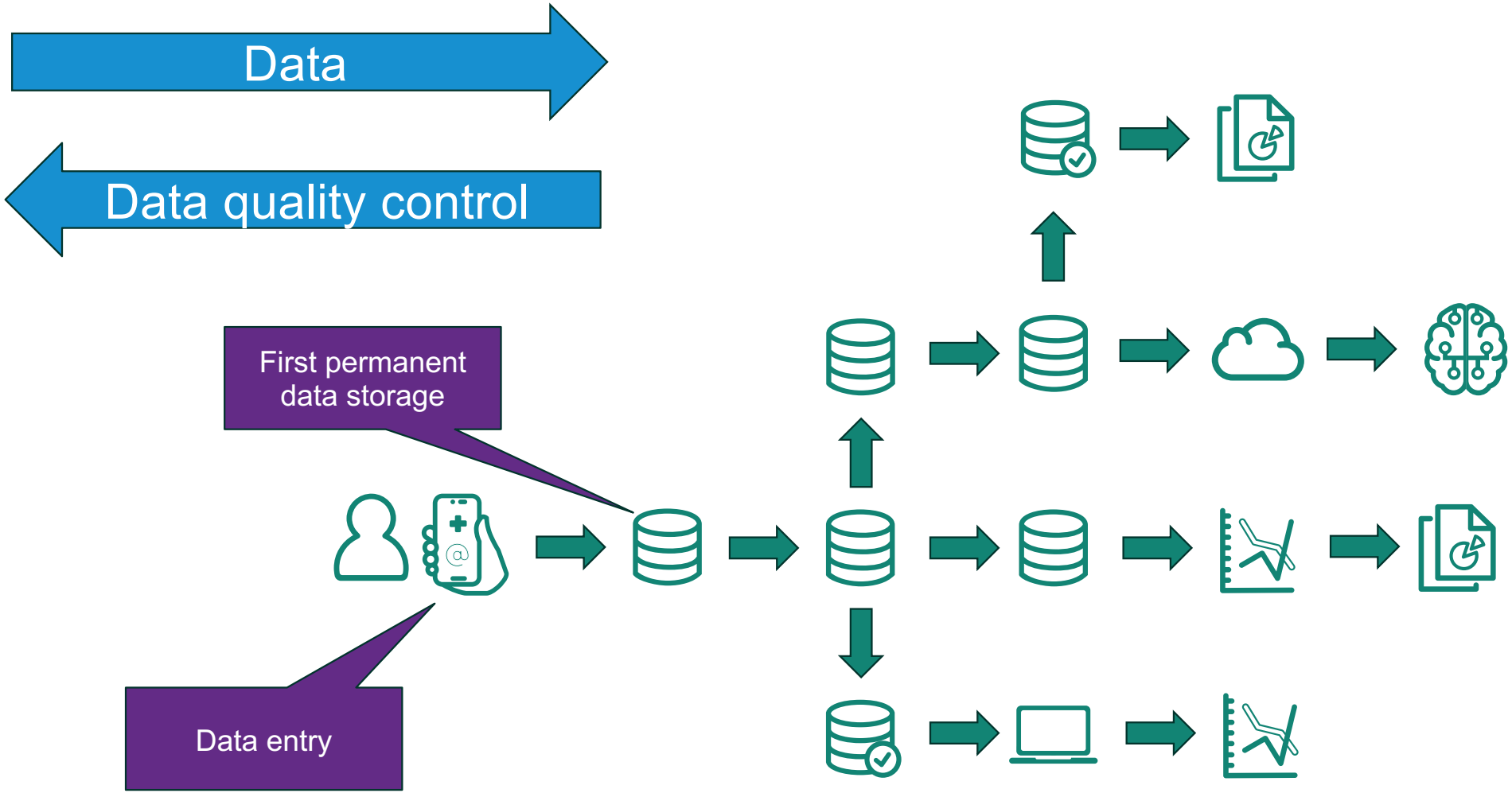
Regulatory background: data corrections

- Patient reported value: 9.8°F (-12.3°C)
  - ☒ Can the value be auto-corrected by the system to 98°F (36.7°C)?
  - ☒ Can the value be auto-corrected by the CRO to 98°F (36.7°C)?
  - ☒ Can the value be auto-corrected by the sponsor to 98°F (36.7°C)?
  - ☒ Can the value be auto-corrected by the site - PI or delegate to 98°F (36.7°C)?
  - ☑ Can the value be corrected to 98°F (36.7°C) after a documented clarification with the patient?
  - ☑ Can the value be excluded?

Case study: eDiary body temperature measurement

- Data correction steps
  - Data QC – issue identification
  - Alignment with the sponsor
  - Internal alignment PM, data management, biostats, QA
  - Request for clarification to the site
  - Data change request (CRO, sponsor, PI approval)
  - Data change
  - Data re-synchronization
  - Additional source data verification
  - Data QC

DCT data flow



Key takeaways

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- For decentralized trials, good design is the key to success
- Data quality should be controlled as early in the process as possible, ideally at the point of initial data entry
  - What is the earliest point in time / data flow where I can implement this check?
- Multiple levels and methods of data quality control must be employed to ensure data validity and acceptability
- Data integrity must be ensured throughout the data flow
- Good risk management process is required on all stages of the study

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