

ACCURACY

- **Avoid duplicate** data entry errors
- **Prevent back-filling or forward-filling of entries** by imposing specified time windows for data entry
- **Decrease missing or unusable entries** by not allowing out-of-range, contradictory, or extraneous responses
- **Ensure that relevant questionnaires are displayed** according to the patient population and the timing of the study using accurate branching logic programming



COMPLETENESS

- **Reduce missing data** thanks to compliance features, e.g. automatic reminders
- **Increase study patient reports** through increased likelihood of reporting more events (and more serious events) electronically than by paper^{4,5,6}
- **Enhance data collection** thanks to the portability of the electronic device compared to easy-to-forget and easy-to-lose paper sheets



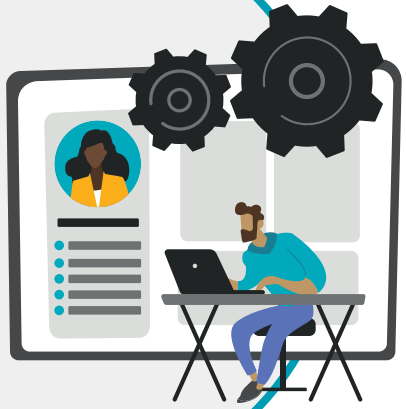
TIMINGS

- **Timely data capture** thanks to pre-programmed data entry windows according to the study schedule
- **Relevant reminders** support users in timely completion of eCOA questionnaires
- **Audit trail of the day/time of data entry** for quality purposes



ATTRIBUTABILITY

- **Restricted access** thanks to individual credentials
- **Access according to the relevant role** of each participant (patients / caregivers), or site staff
- **Access can be managed** according to the status of each individual throughout the study



The strengths of electronic Clinical Outcome Assessment (eCOA) versus paper solutions

USER-FRIENDLINESS

- **Strong preference of study participants for eCOA** as more flexible than paper^{1,2}
- **Possibility for study participants to use their own phone³** in a 'Bring Your Own Device' (BYOD) approach or complete their questionnaires using a provisioned device or a webCOA solution
- **Easier implementation of skip patterns and reduced logistics burden** (no printing and shipping of heavy piles of paper)



REGULATORY COMPLIANCE

- **eCOA systems are recommended by regulatory agencies**
 - Because electronic data collection methods allow more robust data to be obtained
 - Because the usefulness of digital tools and decentralized procedures has been proven in clinical trials⁷
 - Because eCOA systems reduce study patient fatigue and burden, and better engage them throughout the study⁸



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