

## 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

## 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

## USER-FRIENDLINESS

- **Strong preference of study participants for eCOA** as more flexible than paper<sup>1,2</sup>
- **Possibility for study participants to use their own phone<sup>3</sup>** 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)

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

## 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<sup>4,5,6</sup>
- **Enhance data collection** thanks to the portability of the electronic device compared to easy-to-forget and easy-to-lose paper sheets

## 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

## 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 trials<sup>7</sup>
  - Because eCOA systems reduce study patient fatigue and burden, and better engage them throughout the study<sup>8</sup>

<sup>1</sup> Hollen PJ, Gralla RJ, Jones RA, Thomas CY, Brenin DR, Weiss GR, et al. A theory-based decision aid for patients with cancer: results of feasibility and acceptability testing of DecisionKEYS for cancer. Support Care Cancer Off J Multinatl Assoc Support Care Cancer. mars 2013;21(3):889-99. - <sup>2</sup> Richter JG, Becker A, Koch T, Nixdorf M, Willers R, Monser R, et al. Self-assessments of patients via Tablet PC in routine patient care: comparison with standardised paper questionnaires. Ann Rheum Dis. déc 2008;67(12):1739-41. <sup>3</sup> <https://kayentis.com/patients-are-ready-for-byod-are-you/> - <sup>4</sup> Klimes-Dougan B. Screening for suicidal ideation in children and adolescents: methodological considerations. J Adolesc. août 1998;21(4):435-44. - <sup>5</sup> Mazze RS, Shamooh H, Pasmanter R, Lucido D, Murphy J, Hartmann K, et al. Reliability of blood glucose monitoring by patients with diabetes mellitus. Am J Med. août 1984;77(2):211-7. - <sup>6</sup> Given JE, O'Kane MJ, Bunting BP, Coates VE. Comparing patient-generated blood glucose diary records with meter memory in diabetes: a systematic review. Diabet Med J Br Diabet Assoc. août 2013;30(8):901-13.;30(8):901-13. - <sup>7</sup> FDA: <https://www.fda.gov/science-research/science-and-research-special-topics/digital-health-technologies-dhts-drug-development> - EMA: [https://www.ema.europa.eu/en/documents/presentation/presentation-eu-recommendations-decentralised-elements-clinical-trials-m-al-ccmo\\_en.pdf](https://www.ema.europa.eu/en/documents/presentation/presentation-eu-recommendations-decentralised-elements-clinical-trials-m-al-ccmo_en.pdf) - <sup>8</sup> FDA: 1- <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices> - <https://www.fda.gov/media/159500/download>