
Digital Technology in Clinical Trials
August 18
DIA

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# Panel Moderator and Members

- Moderator-Jules Mitchel (Target Health, LLC)

- Panel Members
  - Michelle Eli (Eli Lilly and Company, Chorus)
  - Jonathan Helfgott (John Hopkins University)
  - Susie Song (Biogen)

# Talking Points

- A Case for e-consent-Pros and Cons
- Fit for Purpose-one size eICD does not fit all
- Consent in the era of COVID-19
- FDA e-consent app
- Case Studies and experiences

# Electronic Informed Consent-Pros and Cons

- Pros
  - Electrically available to patients
  - Virtually eliminates use of incorrect version of ICD
  - EDC system activated for patient only after eICD was signed (platform/provider specific)
  - Signed version can be automatically uploaded into TMF(platform/provider specific)
  - Audit trail-Time and date stamp
  - Less paper at site
  - Sites like this once they become acclimated
  - Device agnostic (platform/provider specific)

- Cons
  - Additional IRB approval day(s) of screenshots at study onset
  - Could add to timeline and budget
  - Some countries may not allow e-signatures
  - Still need option for paper in case patients prefer paper or internet goes down

# Fit for Purpose-One Size does not Fit All

- Format of eICD should be customized to fit study design, budget and timeline needs

  - Video/animation with active links
    - Good option for later phase trials that may have complicated ICDs where animation/videos can be helpful in explaining visits, etc…
    - Patient can click on live links and get additional information and sponsor can see where additional explanation might be needed based on number of “hits”
    - Long upfront start up time and can be costly
    - Audit trail
    - Patient and Consenter signature with time/date stamp on each page

# Fit for Purpose-One Size does not Fit All (cont.)

- Format of eICD should be customized to fit study design, budget and timeline needs

  - Site specific .pdf version of approved ICDs loaded into EDC (previous versions become unavailable)

    - Great option for early phase trials
    - Patient can click on section and ask questions that are sent directly to site staff
    - No extra time and minimal cost
    - Changes can be made quickly
    - Audit trail
    - Patient and Consenter signature with time/date stamp on each page

# Fit for Purpose-One Size does not Fit All (cont.)

- Format of eICD should be customized to fit study design, budget and timeline needs

  - Remote eConsent – allows informed consent process to be run virtually
    - Superior delivery of informed consent comparing to traditional phone or fax methods
    - Good option for virtual study or when onsite Informed Consent is not required
    - Possible to use on smartphones, tablet or computer
    - Ability to provide a copy of informed consent and educational component prior to study visit
    - Audit trail
    - Patient and Consenter signature with time/date stamp on each page

# Fit for Purpose-One Size does not Fit All (cont.)

- Vendor selection customized to fit study design, budget and timeline needs

  - CRO owned eConsent platform provides operational advantage if most of clinical operation work is already outsourced to the same CRO
  - Off the shelf integrated eConsent platform provides advantage over made to order approach
  - Single preferred vendor Vs. flexible vendor model
    - Single vendor could provide long term consistency and stability
    - Flexible approach can provide cost benefits depending on study design/needs

# Fit for Purpose-One Size does not Fit All (cont.)

- Making it fit….. Many considerations!
  - eConsent format
  - Vendor
  - Pilot vs. wider roll out
  - Cost and budget
  - Timeline consideration
  - Success measures
  - Study design
  - Participant consideration

# Consent in the era of COVID-19

As sites learned more about transmission of the virus, many sites no longer allowed paper into patient's rooms making eICDs a necessity

- Sites would place iPads in plastic bag as nurses go into COVID room
- Patients log in and sign (if able)
- Plastic bag/gloves replaced site processes

# FDA eICD application

"FDA MyStudies" application

"The FDA is pleased to offer this application to enable electronic consent for COVID-19 trials."

https://www.fda.gov/drugs/science-and-research-drugs/covid-mystudies-application-app

# FDA Guidance on *Use of Electronic Informed Consent Q&As*

- Provides recommendations on use of electronic systems & processes that may employ multiple electronic media to obtain informed consent.
- FDA's requirements for electronic records/electronic signatures, informed consent, and IRBs are set forth in 21 CFR parts 11, 50, and 56, respectively.
- The eIC must contain all elements of informed consent required by HHS and/or FDA regulations (45 CFR 46.116 and 21 CFR 50.25).
- Electronic informed consent may be used to either supplement or replace paper-based informed consent processes in order to best address the subject's needs throughout the course of the study.
- The procedure for eIC may include an electronic method to capture the signature of the subject or the subject's LAR.

# Eli Lilly, Chorus eICD Case Study

- Phase 2a study in 120 Atopic Dermatitis patients in US (8 sites) and Japan (3 sites)
  - Japan did not allow e-signatures for eICDs

# Eli Lilly, Chorus eICD Case Study

- eICD Format
  - .pdf file (Fast to implement)
  - Participant and site personnel e-sign each page
  - Device agnostic
  - Participants could ask questions regarding certain section electronically
  - Only active ICD available for signing
  - Participant eCRFs not available until eICD signing completed
  - Signed version automatically routed to eTMF and could be printed, if desired

# Eli Lilly, Chorus eICD Case Study

- Uptake at US Sites
  - 65% of Participants e-signed ICD
  - 35% signed paper ICD
  - Overall site feedback was very positive

# Keys to success

- On-site start ups at each site
  - Understood site workflow and how e-systems would be integrated
  - Helped them understand all of the regulations were being met and where/how to find all of the info in case of an audit
  - Sites appreciated the 1:1 time and were eager to partner with us to make this work
- e-ICD format was fit for purpose and changes, if needed, could be quickly implemented
- Flexibility enabled wet-ink signature per Japanese Regulatory Requirements
- Ensured sites had a way to use paper if the patient was uncomfortable with e-sigs