

BICS

THE BUCHAREST
INTERNATIONAL
CLINICAL TRIALS
SYMPOSIUM

14 NOVEMBER 2025
Hybrid Event

eConsent





Florin Petrutiu MIT, CISSP

- Over 20-years in site technology leadership
- Designed and built SiteCentric CTMS
- Lead the technology revolution at our site-networks
- Designed/Operated patient-facing data collection technology for 2 large gastroenterology trials
- Supported over 3500 trials and 54 FDA audits

fpetrutiu@sitecentric.com

+40 756-134-611

SiteCentric
C T M S

CNS
HEALTHCARE





eConsent

The scope of where eConsent provides a true benefit is narrow. There are very few scenarios where it can provide a true, tangible and undeniable benefit, namely:

- Enables Decentralized Clinical Trials (DCTs)
- Hybrid Trials (remote re-consents/remote consents)
- Working with young or elderly
- Large participant volume trials (like the COVID vaccine trials)

In many cases, eConsent proves to be counter productive when used in a face-to-face setting with the patient, inside the clinic.



Evaluating Patient-facing Technology

Value to Patient

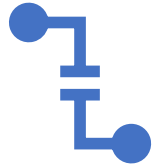
- Location independent
- Curated explanation of the protocol

Value to Sites

- Efficiency Improvement (less time spent on consent)
- Enables remote consenting

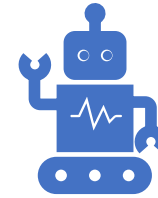
Effect on Trust/Retention

- Negative effect on trust as we distance the clinician from the patient
- Technology burden on patient has a negative impact on trust/retention
 - «Multiple-systems fatigue»: ePro, IRT, eConsent, telehealth apps, etc.



Due to the lack of interconnectivity between systems, island systems create data silos, operational inefficiencies and potential for trial errors.

Accent should be put on all-in-one systems that allow interconnectivity and workflow-oriented approach



Artificial Intelligence (AI) is making an entry into every aspect of clinical trials, even eConsent. Systems like Google NotebookLM have already been employed to explain protocols for staff training, it is not far-fetched to that eConsent and patient-facing applications will soon be employed

(just as fast we one can figure out the ethical and regulatory implications)



Q&A

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