Reinvent Consent

enroll™
Modernizing the consent process has big advantages for patients, sponsors and sites.
Patients are the focus of consent
informed consent
Device Distribution and Training

[Map of the United States with red stars indicating locations]
Handles Versions and Amendments
Network Storage
Sponsors Access Consent Data
Project Teams Can Track Consent Activity
• US and International sites
• Translations in multiple languages
• Partnership with inVentiv Health allows reach in many countries
ROI Opportunities....

- Much faster recruiting
- Consent language learnings
- Amendment management
- Site management/selection
- CRA oversight/remote monitoring
- Risk calculations
- Better patient retention

That’s what I’m talking about!

Sponsor
Validation Study Evidence!

- Randomized trial @ Sutter Hospital in California
- Measured recall of study details 24 hours after consent
- 58% correct answers in Paper Group vs. 75% in iPad Group

58% 75%

\( p = < .01 \)
Recognition

Frost & Sullivan

BEST PRACTICES AWARD

2013

NORTH AMERICAN CLINICAL TRIALS PRODUCT LEADERSHIP AWARD
Regulatory Support

“We support this novel approach.”
“This is precedent setting.”

Reviewed by >30 additional local and academic IRBs
Regulatory Compliance:

- IRBs consider eICF signature as synonymous to handwritten signature per 21 CFR Part 11
- Mytrus supports video capture and photo capture of consent where required by emerging regulations
- No PHI stored on devices
- All data stored on off-site databases to comply with HIPAA
- Maintain security through mobile device management to control all settings and physically locate device at all times
enroll
Demo