

Patient Cloud®: Implementation Challenges and Other Lessons from Beyond Go-Live

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PROMETRIKA: Who We Are

- Full-service CRO located in Cambridge, MA
- Medidata Gold Services Partner
 - Accredited in Rave®
 - First Accredited Patient Cloud® Partner



Patient Cloud Implementation Team



Database Builder



Data Manager



Project Manager (That's me!)



Facts

- 1. Building the Patient Cloud questionnaires is more or less just like building a form in Rave.
- 2. Same goes for testing the build.
- 3. No specialized equipment necessary as you can use the app on almost any mobile device.
- 4. All this leads to shorter timelines and lower costs!

But...no one is perfect.

Medidata is not a dedicated ePRO vendor.



Murphy's Law

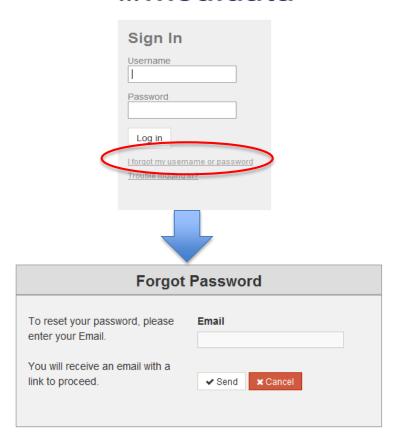
- Your patient can and will forget his email address, username, password, and security answer....at the same time.
- Your site will break every carefully written and strategically placed edit check.
- The only time your Wi-Fi dies is the day you need the questionnaire data for randomization.

Plus so much more!



Lesson #1: Resetting Logins

::: medidata







Lesson #1: Resetting Logins

- Help desk is not equipped to handle username/password reset requests from patients.
 - If you can't self-reset, it could take days for Medidata to retrieve that information in the back end.
- Take preventative action against forgetful patients
 - Learn how to do simple log in retrievals, but understand the limitations of self-service process.
 - Develop a process by which the patient is asked to write down information somewhere private and secure.
 - Encourage use of the new PIN system.



Lesson #2: Learning the Technical Stuff

(I'm talking to you, ClinOps)

- During the build
 - Participate in edit check design
 - Order of questionnaires
- Post go-live
 - Learn your edit checks!
 - Username cache
 - Patient Cloud Gateway
 - Who troubleshoots what





Lesson #3: Site-level Challenges

- Questionnaires administered at the site: Who's providing the devices
- CCGs
 - Both CRAs and CRCs must understand order of operations for navigating around edit checks
- Leverage the experience of your CRAs and CRCs to help identify potential issues
 - Patient population issues
 - Email address confidentiality
 - Connectivity issues



Lesson #4: Device Setup

Devices at Site

- Provisioning vendor
- Wi-Fi or cellular
- Initial device registration
- Turning off device features
 - Predictive typing/auto correction
 - Auto update
 - Notifications

Personal Devices

- Troubleshooting
- App version control
- Turning off device features
 - The patient may want these features on!





Lesson #5: Prepare for the Worst (or "Risk Mitigation" if you're a Project Manager)

- Be careful about relying on data to make time-sensitive assessments
 - Screening/randomization eligibility
 - Course of treatment
- Pilot the app
- Paper back-ups
 - Core configuration implications
- Mapping/reconciling the data in the back end



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