



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.

5. 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

Sign In

Username

Password

[I forgot my username or password](#)

[Trouble logging in?](#)



Forgot Password

To reset your password, please enter your Email.

You will receive an email with a link to proceed.

Email

Recover Account

medidata
PATIENT CLOUD

Forgot your Email
If you do not know which email to use, please contact your provider.

Forgot your Password
To reset your password, enter your email. You will receive an email from Medidata with instructions on how to reset your password.

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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