

# Converting the Protocol Deviation Tool (PDT) to a Mobile Application

## Introduction

This is a conceptual overview of my user experience design process and the selective challenges (project scope, device limitations, desired functionality, etc.) necessary to convert an existing enterprise-based, desktop/laptop application to an improved mobile Web experience. I'll use a smart phone-sized screen to force "mobile first" design choices.

For this overview, I will focus on Phases 1–3 (research, architecture and design, as noted below, as well as on my resume).

The desktop/laptop application discussed here is PAREXEL's "Protocol Deviation Tool" (PDT Release 2) and the mobile application we'll call "PDTM R3" ("M" for mobile, Release 3).

- Phase 1: **Research**
  - Top-down Research of Business Goals and Requirements
  - Heuristic Review of an Existing or Competitor's Application
  - Bottom-up Research of User Needs and Constraints
- Phase 2: **Architecture**
  - Information Architecture
  - High-level Application Screen Layout
- Phase 3: **Design**
  - Paper Sketch to Whiteboard to Wireframe and/or Prototype
  - Annotated Wireframes and/or Prototype as User Journeys
- Phase 4: **Validation**
  - Usability Test Script
  - Usability Report

# Selective UXD Process Overview — Desktop/Laptop to Responsive

## Heuristic Review

Not only is a heuristic review necessary to look at and critique the existing application, but this activity focuses the team on the critical mobile functionality for users. As will be seen, some of the functionality should be implemented on the desktop/laptop Web app in a later release (e.g., R4, R5, etc.).

## What the Original PDT R2 Application Does

- The Protocol Deviation Tool (PDT) monitors key criteria and sub-criteria (e.g., compliance and legal issues; timely logistics; adverse events (AEs) that do not require hospitalization; serious adverse events (SAEs) that do require hospitalization; etc.) as defined by appropriate personnel. This monitoring occurs while a clinical trial is under way.
- Data results are manually filtered and sorted by the user to initiate reactive measures as needed.

## What the Original PDT R2 Application Does Not Do, or Does Not Do Well

- There are not enough proactive mechanisms to assist the user to spot, determine, react, etc. to any AEs and SAEs via dashboards, visualizations, alert mechanisms, pre-defined/changeable settings, etc.
- The application is too tabular data heavy in its data display, forcing the user to wade through columns of data to filter, search and sort in order to affect a reactive plan of action.
- The application relies on the import/export of Excel spreadsheets to manage the volume of data — again, the user must manually filter, search and sort in order to affect a reactive plan of action.

# Selective UXD Process Overview — Desktop/Laptop to Responsive

## Challenges for this Conversion to PDTM R3

Like many Web-based applications, the reduced working area from a full-screen monitor to a tablet- or phone-sized screen present challenges, options and opportunities to fine tune its UX: system architecture, information design, task flows, etc.

- **What Features to Keep and New Features to Add**

- **Create** — Allow a user to create new protocol deviation (PD) via user-entered criteria. Multiple PDs are viewable in the dashboard, but for simplicity, I'll just show a single PD.
- **Dashboard** — This is a new feature to the responsive adaptation. It is a better means to proactively determine problems with an on-going clinical trial in real time that does not involve wading through columns of data.
- **Search** — An improved and reduced-in-size variation of the original vanilla search tool. This allows users to add themselves to other projects, etc.

- **What Features to Remove**

- **Excessive Data Entry** — especially if a majority of users will use their phones to simply “check on things”.
- **Excessive Columns of Data** — this converted application should not reinvent the wheel of Excel, nor show large volumes of tabular data.

- **What Features were Not Added to this Version**

- **Visualizations** — Insufficient screen real estate for complex SpotFire- or Tableau-style visualizations even with “zoom in” and “zoom out” capabilities. The dashboard is a compromise. An R4 version that could detect screen size and from that enable visualizations would be a possible solution (or via a user preference).
- **Internal Message System** — This will be added to R4 either as part of PDT (as seen in R1–2), or linked to a user’s actual email system. Integrated messaging is preferred as users can send each other PD settings for approval, consultation, system alarm settings, etc. as well as send alerts to colleagues and managers.
- **App Administration (User, System, PD Ranges, etc.)** — These will be added to R4 or R5 for high-level system control by “super users”.

# Protocol Deviation Tool as a Mobile App – Phase 3: UX/UI Design – Source App Image

William Scammell – User Experience Designer

**PROTOCOL DEVIATION TOOL** Welcome PCDA Joe Sample | Logout

Client Program Study Period Load

Export To DV Data Set Export All Study PDs

REVIEW TREND ANALYSIS STUDY SETUP ADMINISTRATION STUDY PROFILE

Change PD Review Status Export To Excel

Days Without Review	Source System	Country	Principal Investigator	PRXL Site References	Subject Number	Visit Ref.	Suggested Category	Assigned Category	Sub Category	PD Review Status	PD Status	Last Updated Date	Created Date
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Protocol IDL: 123456; PRXL Site Reference: 123456; Principal Investigator: Don Deluca; Severity: Major; Issue Category: 10; PD Spec Ref ID: -; Unique PD ID: 7262

**PD Review History**

LBST Reviewed by Simon Fear on 21-Mar-2013  
I agree with you all.  
Assign Category major by Simon Fear on 21-Mar-2013  
COL Reviewed by Maggie Smith on 20-Mar-2013  
No comments

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**Comment – Source Image**  
Sample high-fidelity mockup from Protocol Deviation Tool R2 which is the starting point for the conversion to a mobile application.

# Protocol Deviation Tool as a Mobile App – Phase 3: UX/UI Design – Paper Sketches

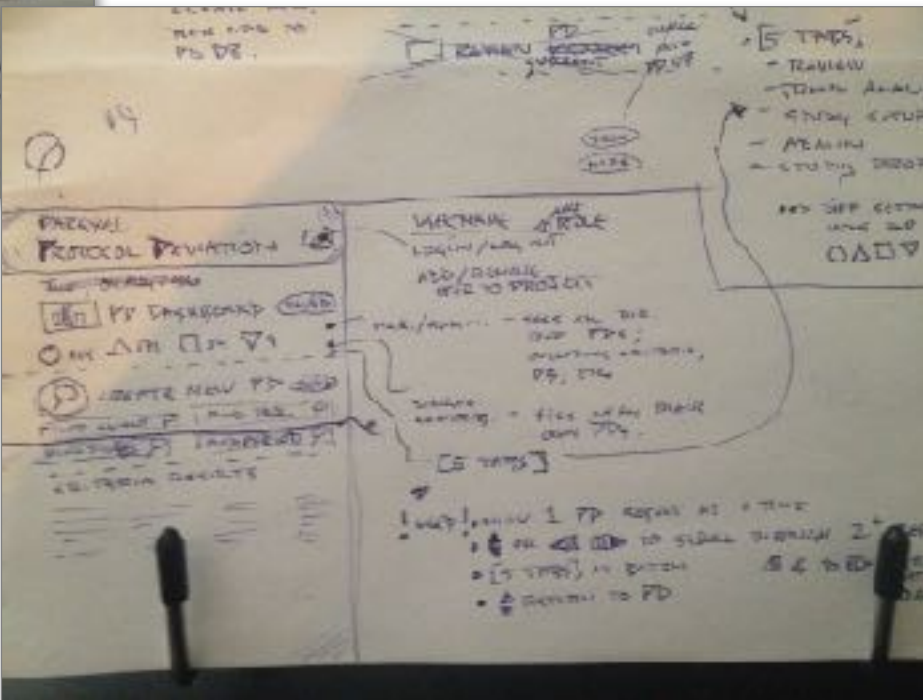
William Scammell — User Experience Designer



## Discussion

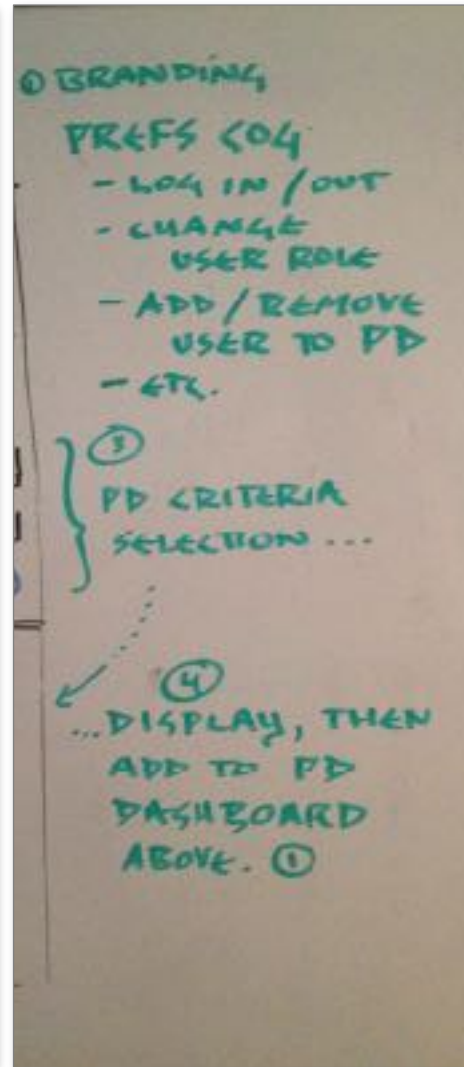
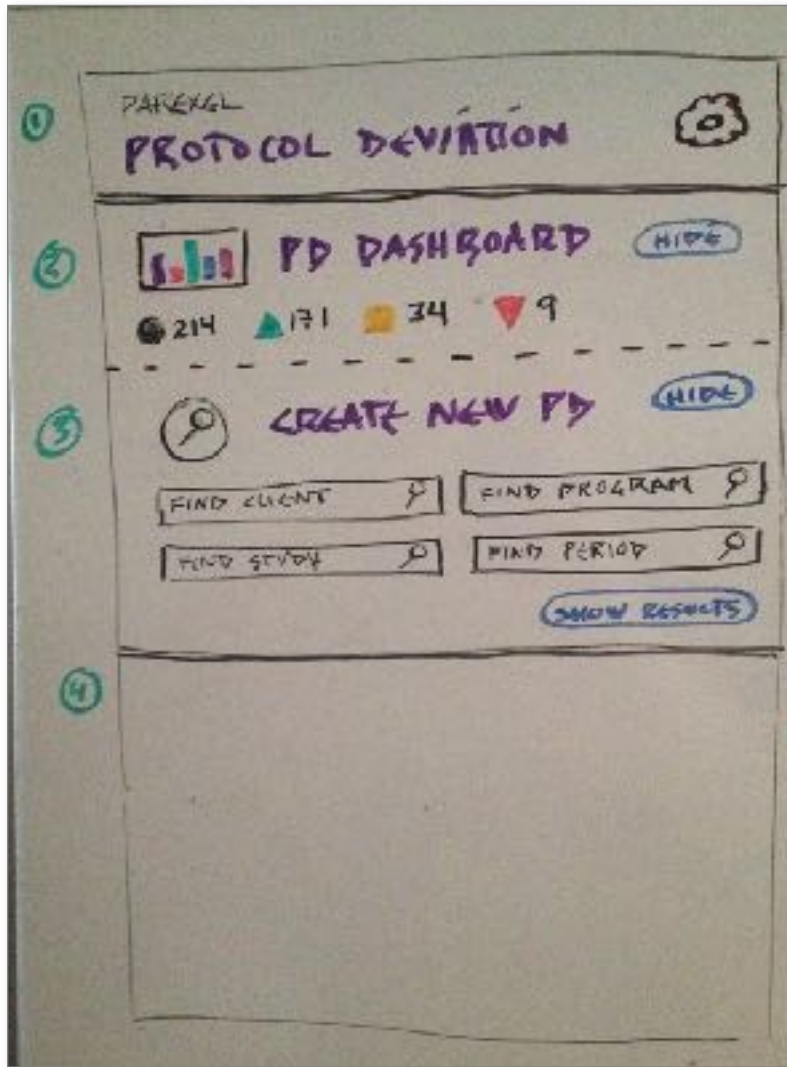
Because users will want to “check in” on their various clinical trials several times each work day, and dare we say weekends too, I started with the Status Dashboard and built out the Find and Create functionality later.

Don't worry, things get more neat and legible in later pages. For now, just bask in the glow of my scribbles, doodles, notes and arrows as I merge business requirements (top-down design) with user needs and UX best practices (bottom-up design).



# Protocol Deviation Tool as a Mobile App — Phase 3: UX/UI Design — White Board Sketches 1a

William Scammell — User Experience Designer

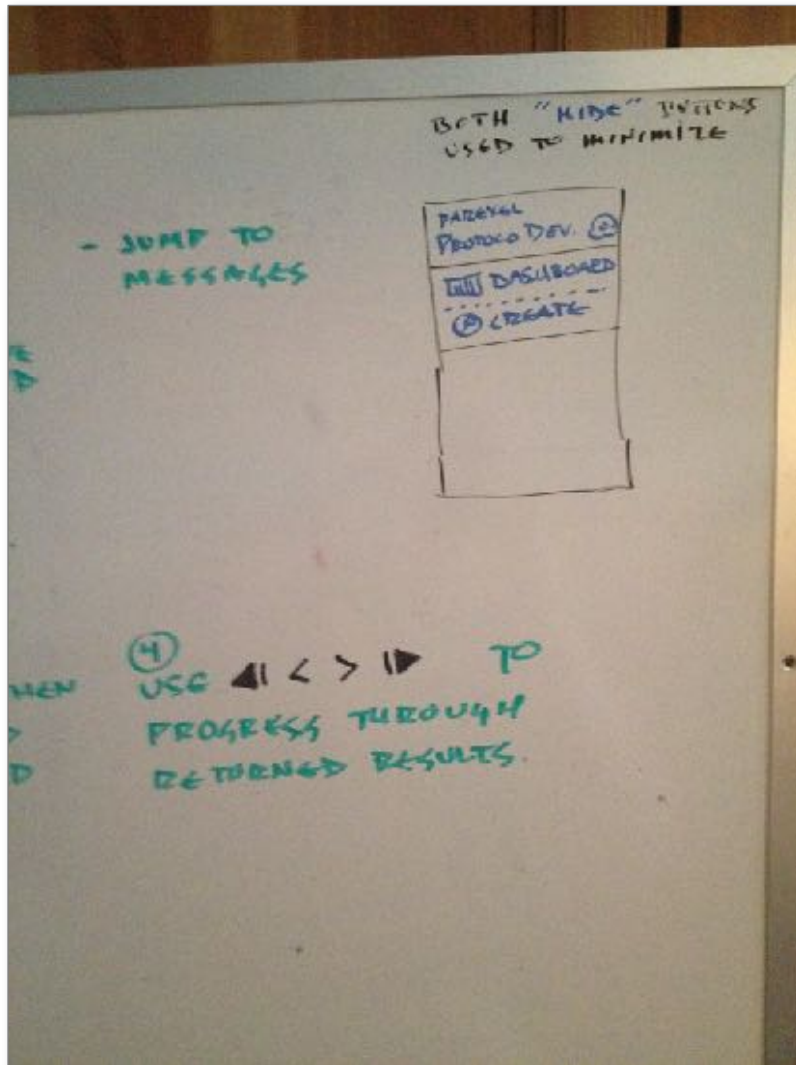


## Discussion

Now it's time to neaten the paper sketches and move them to a white board for further refinement including some error checking, functional task flows, information design, system architecture, etc. while working through how the user easily journeys through the system to complete tasks.

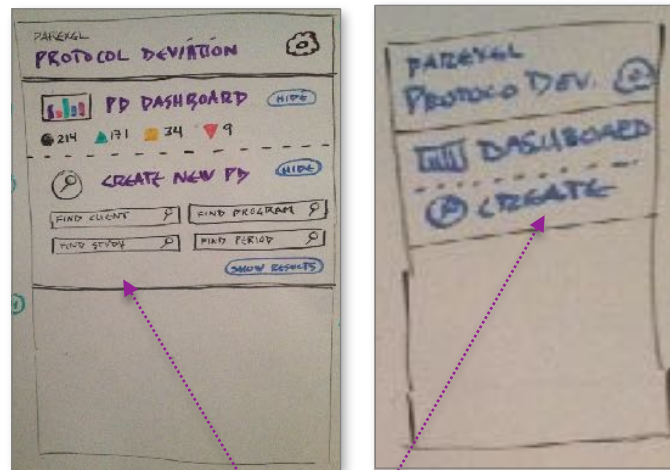
# Protocol Deviation Tool as a Mobile App — Phase 3: UX/UI Design — White Board Sketches 1b

William Scammell — User Experience Designer



## Discussion

More notes are added and there are some iterations of buttons and button titles; some changes in dashboard icons; and each sectional "tab" now has an "open" and "closed" view so users can concentrate on just the "tabs" they need to see (typically the PD Dashboard which has been placed at the top as it's the primary function of this mobile app).



### Note — App "Tabs" in Open and Closed Modes

White board sketches of the mobile app with its "tabs" in the open (left) and closed (right) view modes. There will be separate "Hide /Show" buttons in the wireframes.

# Protocol Deviation Tool as a Mobile App – Phase 3: UX/UI Design – Compare Original App vs. WB Sketches 1

William Scammell – User Experience Designer

The screenshot shows the 'PROTOCOL DEVIATION TOOL' web application. At the top, there is a navigation bar with the title and a PAREXEL logo. Below the navigation bar are tabs for 'REVIEW', 'TREND ANALYSIS', 'STUDY SETUP', 'ADMINISTRATION', and 'STUDY PROFILE'. The main content area features a table with columns for 'Days Without Review', 'Source System', 'Country', 'Principal Investigator', 'PRXL Site References', 'Subject Number', 'Visit Ref.', 'Suggested Category', 'Assigned Category', 'Sub Category', 'PD Review Status', 'PD Status', 'Last Updated Date', and 'Created Date'. Below the table, there are three panels: 'PD Review History', 'PD Description', and 'Additional PD Information'. The 'PD Review History' panel contains text about reviews by Simon Fear and Maggie Smith. The 'PD Description' panel contains a placeholder text for the deviation description. The 'Additional PD Information' panel contains a placeholder text for additional information.

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See next page for comparison notes of what functionality will be seen in PDTM R3.



# Protocol Deviation Tool as a Mobile App – Phase 3: UX/UI Design – Compare Original App vs. WB Sketches 2

William Scammell – User Experience Designer

## Note – Desktop to Mobile Tabs

These 3 tabs become the Dashboard, Find and Create tabs in the mobile app.

The other 2 tabs are for later releases and apply to Super User tasks.

## Note – Create New Protocol Deviation

These sort / filter pulldowns will become smart search fields in the mobile app.

(The smart search fields are available in the PD Dashboard view once that mode is enabled during drill down. See the wireframes in later pages.)

**PROTOCOL DEVIATION TOOL**

Welcome PCDA Joe Sample | Logout

Client Program Study Period Load

Export to DV Data Set Export All Study PDS

REVIEW TREND ANALYSIS STUDY SETUP ADMINISTRATION STUDY PROFILE

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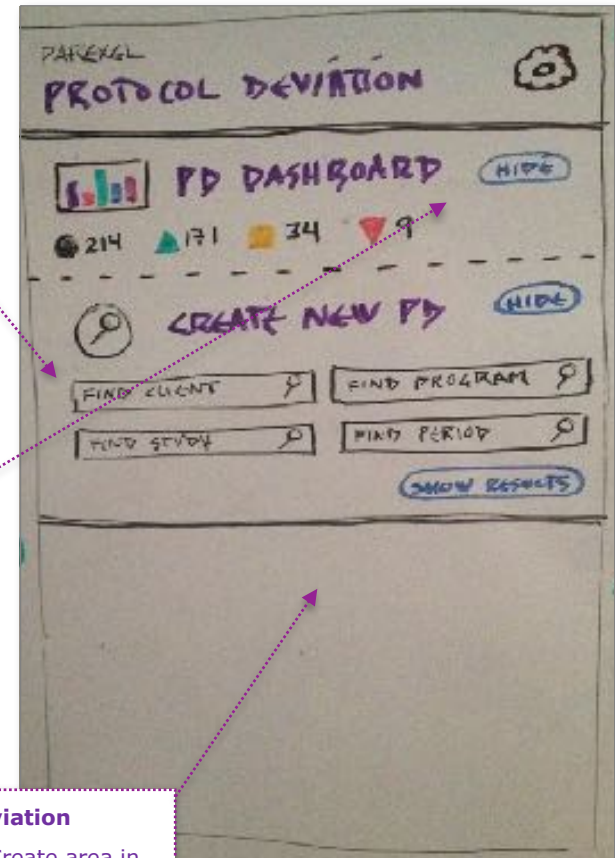
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## Note – Dashboard

There was no dashboard in the R1-2 releases. A dashboard approach is imperative with a phone's small screen and to eliminate the huge tabular data columns.

## Note – Find Existing Protocol Deviation

The Find function splits off from the Create area in the actual wireframes (seen in later pages) to focus the user's attention on that task and because the results involve much different use cases.

# Protocol Deviation Tool as a Mobile App — Phase 3: UX/UI Design — Home Screen with All Views in “Hide” Mode

William Scammell — User Experience Designer

PROTOCOL DEVIATION TOOL
Welcome PCDA Joe Sample | Logout

Right where you need us™

Client 
Program 
Study 
Period 
Load

Export To DV Data Set
Export All Study PDs

REVIEW
TREND ANALYSIS
STUDY SETUP
ADMINISTRATION
STUDY PROFILE

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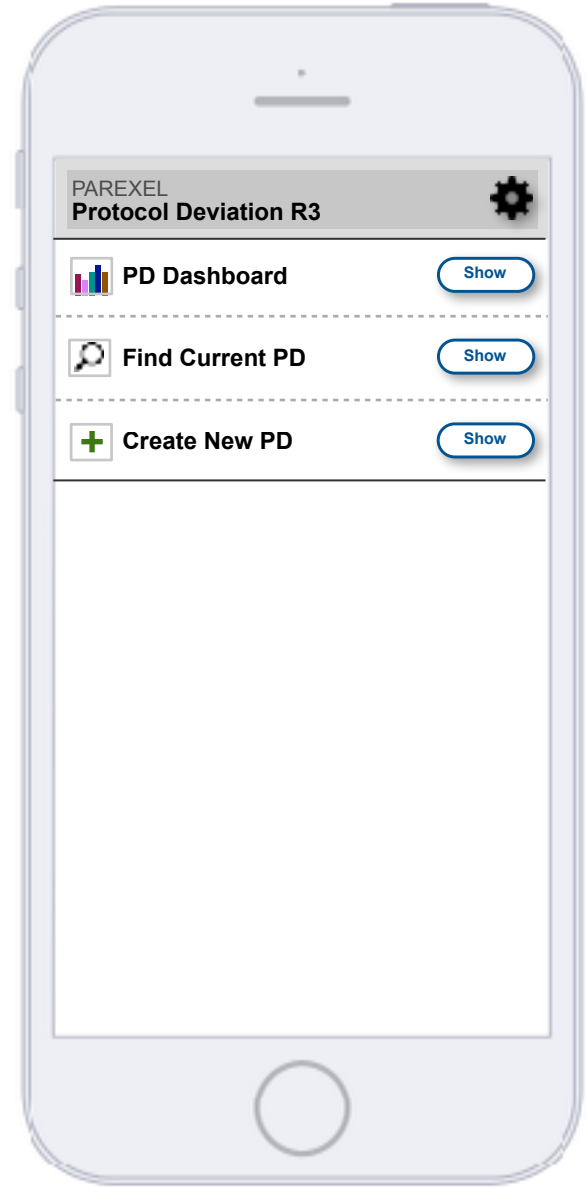
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**See next page for comments**



# Protocol Deviation Tool as a Mobile App — Phase 3: UX/UI Design — Home Screen with All Views in “Hide” Mode

William Scammell — User Experience Designer

## 1-3 — Primary User Areas

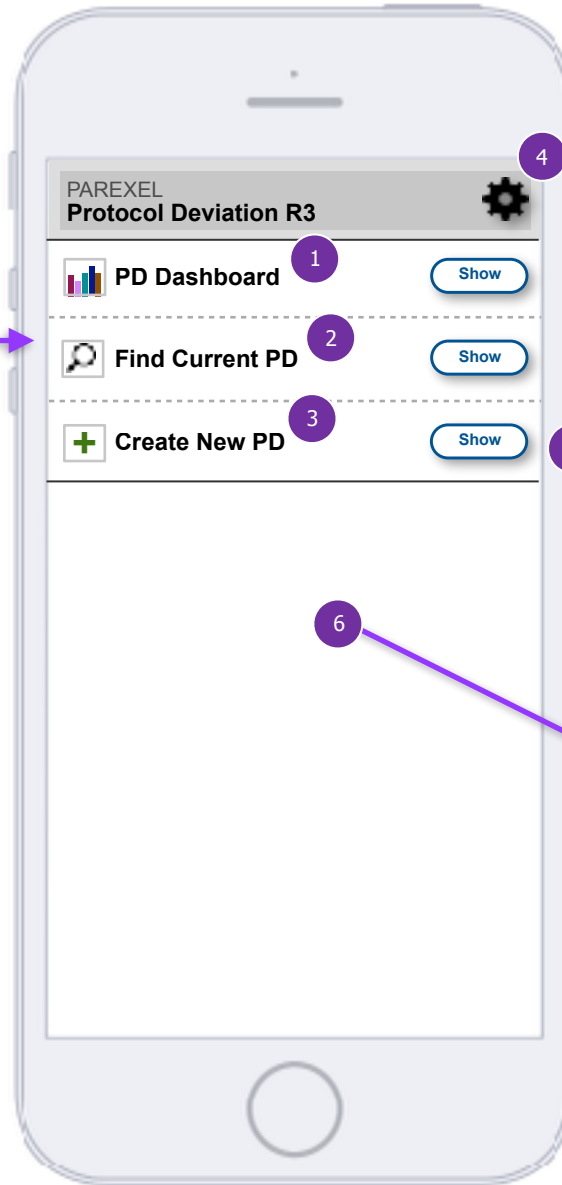
1 — The dashboard (PDTM R3) displays the status of protocol deviations for all ongoing trials that the user is linked to.

2 — The user can find other trials and add themselves so they can monitor more than one trial.

These newly added PDs would show up in the dashboard area. (This process is not shown in this deck.)

3 — Users can also start new PDs based on typical default criteria / settings, or use their own. Users could also set up different settings for the same trial to test theories in a proactive manner.

These newly created PDs would show up in the dashboard area. (This process is not shown in this deck.)



## 4 — Preferences Cog

Seldom accessed user actions and settings via this flyout menu.

- Log In / Log Out
- Change User Role
- Add / Remove User to PD
- etc.

## 5 — “Show” Buttons

The three primary user areas are shown “Open” on the next page.

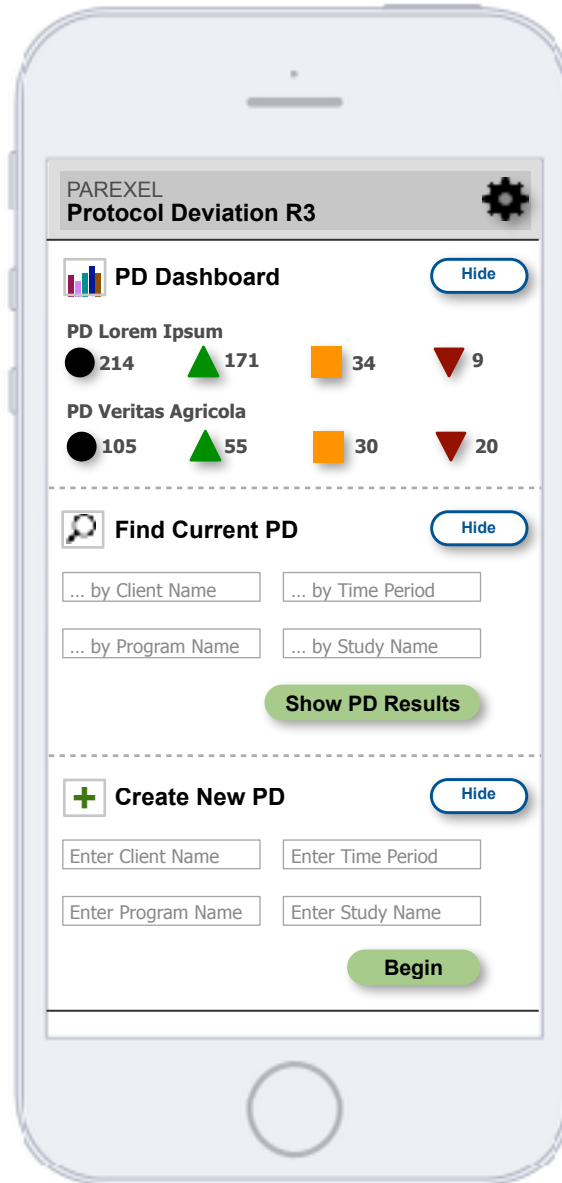
## 6 — Room to Grow

For future expansions (R4, R5, etc.) to this software (visualizations, message area, etc.) and when the PD Dashboard has more than 1 PD to display to the user.

All 3 tabs in their “closed” position

# Protocol Deviation Tool as a Mobile App — Phase 3: UX/UI Design — Home Screen with All Views in “Show” Mode

William Scammell — User Experience Designer



All 3 tabs in their “open” position

See next page for comments

# Protocol Deviation Tool as a Mobile App — Phase 3: UX/UI Design — Home Screen with All Views in “Show” Mode

William Scammell — User Experience Designer

## 1 — PD Dashboard

(A) For clinical trial “PD Lorem Ipsum” the icons refer to:

### Black Circle —

- 214 Total PDs are linked to this PD.
- Clicking on this icon takes the user to an overview screen (not yet shown in this deck) for all linked PDs just the “PD Lorem Ipsum” trial.

### Green Up Arrow —

- 171 of the 214 PDs linked to this PD are above their criteria range.
- Clicking on this icon takes the user to a screen (not yet shown in this deck) for all linked PDs that are above their minimum acceptable range.

### Orange Square —

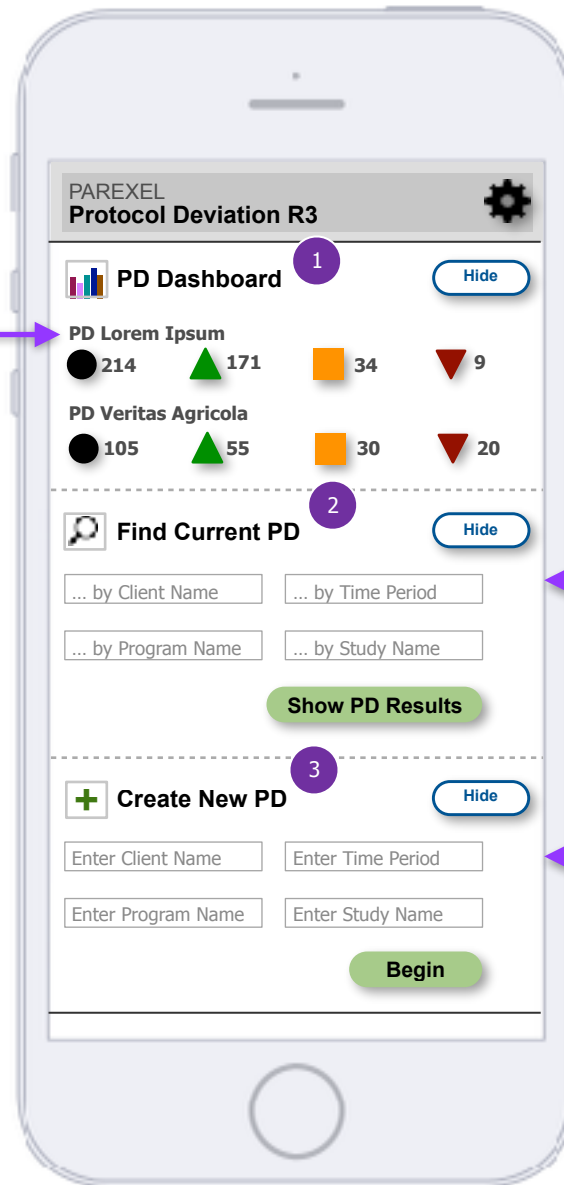
- 34 of the 214 PDs linked to this PD are within their median criteria range.
- Clicking on this icon takes the user to a screen (not shown in this deck) for all linked PDs that are within their range.

### Red Down Arrow —

- 9 of the 214 PDs linked to this PD are below their minimum criteria range.
- Clicking on this icon takes the user to a screen (not shown in this deck) for all linked PDs that are below their range.

(B) For clinical trial “PD Veritas Agricola” the icons refer to:

- Black Circle — 105 Total PDs for this clinical trial.
- Green Up Arrow — 55 PDs above their criteria range.
- Orange Square — 30 PDs within their median criteria range.
- Red Down Arrow — 20 PDs below their minimum criteria range.



## 2 — Find Current PD

The user can find other clinical trials and add themselves so they can monitor the PDs of more than one trial.

Users should enter information into more than one Data Entry Field to find a current PD creation process more quickly.

After the user finds a new PD and adds it to their list, it would appear in the Dashboard area. This process shown is not shown in this deck.

## 3 — Create New PD

Users can start new PDs based on typical default criteria / settings, or use their own. Users could also set up different settings for the same trial to test theories in a proactive manner.

Users enter information into one or more Data Entry Fields to create new PDs more efficiently. After pressing “Begin” a new screen (not shown) would be used to enter various PD criteria to monitor. Once those steps are complete, the new PD would appear in the Dashboard area.