# A Novel Validated Electronic Patient Data Acquisition Tool Standardizes Patient Reported Outcomes (PRO) Data Acquisition Across Multi-Center Environmental Exposure Chamber and Field Studies

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## Abstract

**Rationale:** PRO data is traditionally collected by either paper or computer based systems at EEC sites and is not suitable for use in multicenter or field studies. FDA and EMU guidances require validated PRO data collection tools suitable for use in multicenter or field studies. FDA and EMU guidances require validated PRO data collection tools which are to be used in pivotal multicenter studies. Currently there are no validated PRO tools available which are suitable for multicenter EEC and field hybrid studies.

**Methods:** Tablet computer based PDAT that collects PRO data with a user interface that is large and easy to use. The data is collected and transferred live to a central secure server via a secure wireless link. The development entailed detailed user specifications, usability testing and cognitive testing.

**Results:** We have developed a validated electronic tablet computer based PRO that collects data securely and transfer the data real time to a secure server. The data collection process is CFR21 Part 11 complaint. Data can be collected using traditional categorical scoring and visual analog scale. System is capable of recording GPS co-ordinates of when the data was taken such that we can analyze the environment/location the subject was when the data was collected. Other features include time logging, data entry windows, compliance incentives and follow on questions for the diary card.

**Conclusions:** A validated tablet based PRO system is now available that is specifically designed to conduct single and multicenter EEC, and EEC/field hybrid studies.

## Introduction

Patient-reported outcome (PRO) instruments are a means to capture patient data used to measure treatment benefit or risk in medical product clinical trials.[1] This is usually in a form of a questionnaire with outcomes that are measured in terms that describe the change in symptoms or signs of the medical condition or following research stimulus. Regulatory agencies require that the PRO come directly from the patient as their perception of the disease and its treatment[2] without any interpretation or interference by another is imperitive.[1] PRO data is traditionally collected by either paper or computer based systems at EEC sites. FDA and EMA guidances require validated PRO data collection tools suitable for use in multicenter or field studies. PRO outcomes of nasal and non-nasal symptoms are recommended primary outcomes in allergy research.[3] In this study, an ePRO is validated for use in either single center or multicenter allergy studies.

## Methods

Develop a tablet computer based PDAT that collects PRO data with a user interface that is customizable, large and easy to use. System needs the flexibility to operate seamlessly whether an active internet connection is available or not. Ensure data is collected and immediately transferred to a central secure server in an encrypted and wireless manner. Fully validate entire computerized system with detailed User Requirements and a set of comprehensive User Acceptability Testing (UAT).

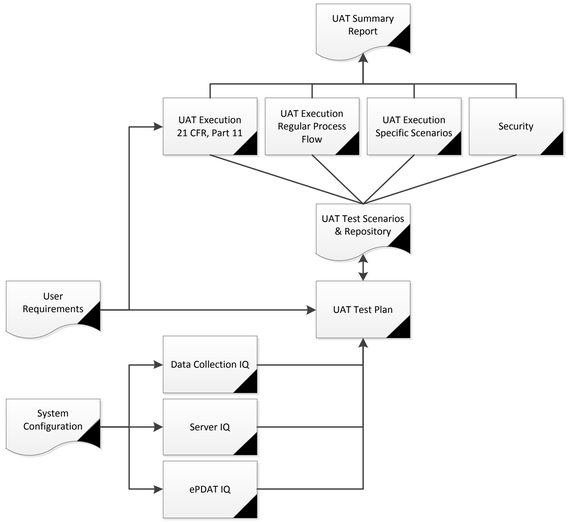


**Figure 1.** Schematic of validation process

## Results

We have developed and validated an electronic tablet-based PRO that collects data securely and transfer the data real-time in an encrypted manner to a secure server in an entirely 21 CFR, Part 11 complaint manner. System is capable of recording geo-positioning data of when the event was performed such that we can analyze the environment/location the subject was when the data was collected. Other features include time logging, data entry windows, compliance incentives and follow on questions for the diary card.

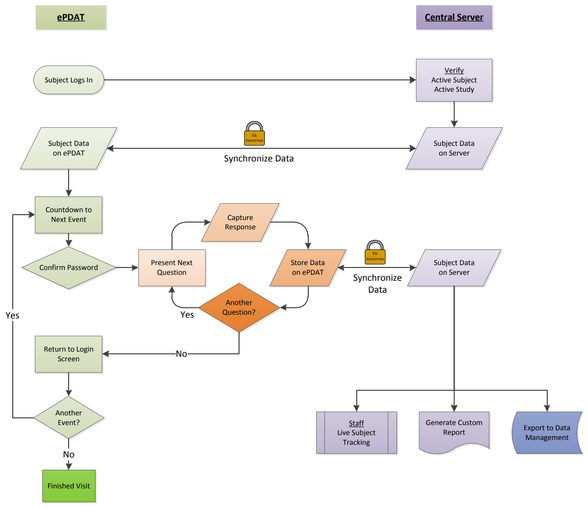


**Figure 2.** Schematic of ePDAT workflow

## ePDAT Advantages

- Single question presentation for ease of patient understanding and response with rating scale instructions repeated just prior to each question
- Faster collection of data values
- Eliminates common errors of transcription
- Time controlled data ensure subject compliance
- Ability to provide follow-up questions with each response
- Instant access to data
- Capability to manage multiple patients with staggered EEC entries easily
- Ability to generate reports immediately and provide data encryption transfers

| Type | Paper Diary | Electronic Diary |
|---|---|---|
| Advantages | • Inexpensive to produce<br>• Subjects/staff familiar with method<br>• 100% customizable to needs<br>• Physical copy always exists | • Faster collection of data values<br>• Instant access to data<br>• Immediate access to customized reports<br>• Time-controlled data entry windows<br>  ○ Promotes subject data entry compliance<br>• Eliminates common human errors<br>  ○ Eg. Transcription, impossible responses<br>• Ability to trigger follow-up questions |
| Disadvantages | • Difficult to manage staggered entries<br>• Transcription (Time & costs)<br>• At-Home Diaries difficult to control compliance<br>• Prone to human error<br>• Archive Costs & Retention Period | • Unit cost for each additional unit<br>• Subjects/staff require additional training to use<br>• Customization limited to technology<br>• Possibility of mission critical failure |

## Results (Continued)

***Actual Screenshots***

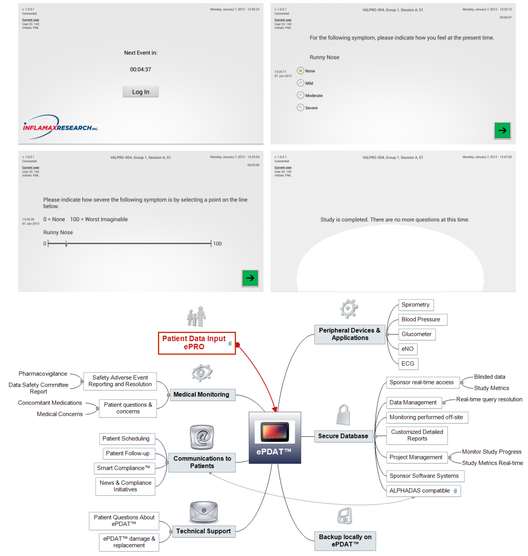


**Figure 3.** ePDAT functionality & connectivity

## Conclusions

A validated tablet-based PRO system is now available that is specifically designed to conduct single and multicenter EEC, and EEC/field hybrid studies.

## References

1. U.S. Department of Health and Human Services, FDA, CDER. Guidance for Industry : Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. December 2009.
2. European Medicines Agency. Reflection Paper on the Regulatory Guidance For the Use of Health Related Quality of Life (HRQL) Measures in the Evaluation of Medicinal Products. July 2005.
3. U.S. Department of Health and Human Services, FDA, CDER. Guidance for Industry : Allergic Rhinitis: Clinical Development Programs for Drug Products. April 2000.

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