

# Advanced Electronic Patient Data Acquisition Tablet for Clinical Trials

**ePDAT™ was developed through a stepwise and accepted process:**

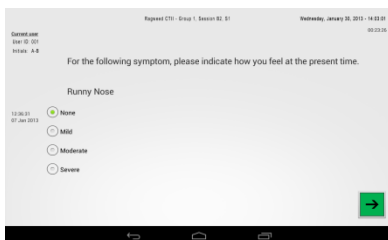
**I. Definition Stage** where user requirements and specifications are determined.

**II. Planning Stage** where a validation plan is developed and then regulatory and risk assessment performed.

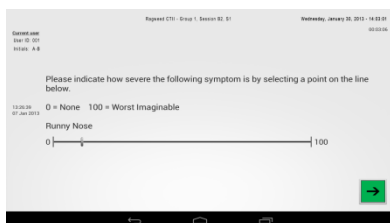
**III. Design Stage** where a system design and testing plan is developed.

**IV. Installation & Configuration Stage** which includes installation qualification and verification of secure, encrypted connection to the central database.

**V. User Acceptance Testing** confirms that the developed tool is indeed performing as originally intended via test scripts and testing as in **Operational** and **Performance Qualifications**.



*Inflammax Research's ePDAT™ allows instantaneous symptom score collection in the EEC and real-time data capture.*



## Inflammax's ePDAT™

Inflammax's proprietary electronic Patient Data Acquisition Tablet™ (ePDAT™) is specifically designed to improve the quality and type of Patient Reported Outcomes (PRO) data collection in clinical trials.

*"At Inflammax Research we saw the need to develop an ePRO system which allowed for the seamless acquisition of patient reported data from patients both at-home and while they are exposed to controlled levels of allergen in our Mobile Environmental Exposure Chambers™. The available ePRO systems did not provide the screen size, graphical user interface or the user experience that we felt would be optimal for today's clinical trial requirements. ePDAT™ is the first e-diary of its kind that combines the latest in tablet hardware and graphical user interface available with software that is FDA compliant and validated for ePRO data collection . "*

Dr. Piyush Patel, Founder & CEO, Inflammax Research

Until now, tablet-based technology of this kind has not been available due to legacy software issues and logistics. Inflammax Research has partnered with Logos Technologies in the UK, leaders in early phase research data acquisition technology, to bring the best of computer tablet technologies with good clinical and documentation practices to ensure compliance with FDA and EMA requirements for validated ePRO data collection tools. ePDAT™ is fully 21CFR Part 11 compliant.

## ePDAT™ Differentiators

### Versatility

ePDAT™ can provide such features as:

- on-screen questionnaires
- visual analog scales (VAS)
- response time metrics
- coordination tasks
- high resolution image capture
- evaluator interview via video conferencing

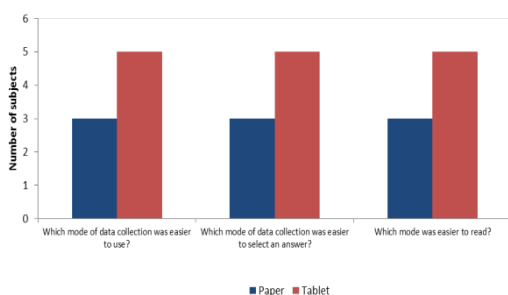
### Data Security

Security features include unique password and freehand signatures. Improved software architecture allows patient data to be uploaded in real-time directly via the tablet's cellular wireless connection to our secure database servers. Data are also stored locally on the tablet as back-up.

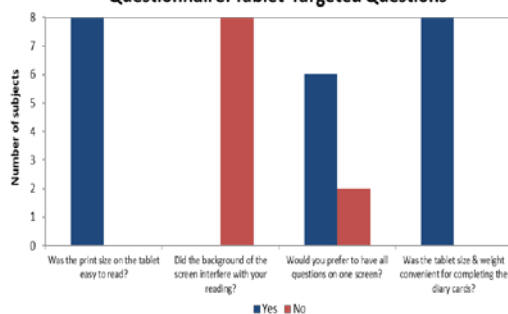
### Advanced Analytics

The ePDAT™ system is also capable of recording geo-positioning data at the time of data entry, which may provide insight into allergen exposure for patients in their generalized vicinity. This can be important in the traditional field approach where the allergic patient's symptomatology is solely dependent on allergen exposure in their everyday lives.

Questionnaire: Paper vs Tablet Diary Cards



Questionnaire: Tablet-Targeted Questions



In a recent study conducted at Inflamx Research, patients were asked specific questions to compare their preference for diary card formats of paper versus electronic diary cards. The electronic format used in this study was Inflamx's proprietary ePDAT™ system. As shown in the graph (upper), the majority of patients preferred ePDAT™ over traditional paper diary cards. 100% of patients accepted and approved of ePDAT™ hardware, software and graphical user interface (shown in graph, lower).



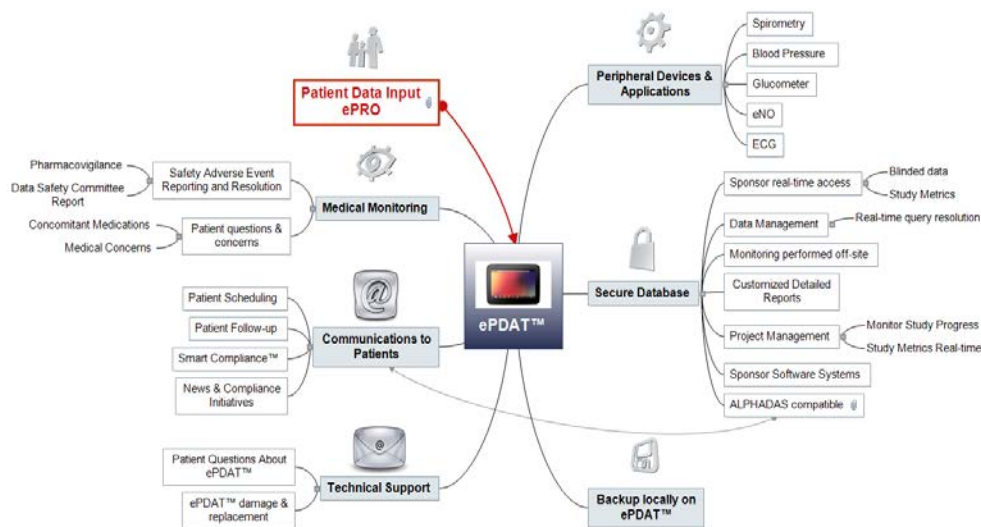
Photograph of ePDAT™ users in an Environmental Exposure Chamber at Inflamx Research headquarters in Toronto, Canada. Subjects are prompted by ePDAT™ to complete questionnaires at regular intervals per protocol. 100% compliance is ensured.

## User Acceptability

In a recent study submitted to the European Academy of Allergy and Clinical Immunology and the World Allergy Organization (EAACI-WAO), ePDAT™ was shown to be accommodated well for symptom reporting by allergic patients asked to rate their allergy symptoms either on electronic or paper formats. As shown in the graph (upper left), patients reported that ePDAT™ was easier 1) to use, 2) to select an answer, and 3) to read. As shown in graph (lower left), 100% of patients reported the following about ePDAT™: 1) print size was good, 2) background screen lighting did not interfere with reading 3) tablet size and weight was convenient for completing diary cards.

## ePDAT™ Integration

ePDAT™ is versatile and compatible with many existing systems such that integration into your study is easy and provides many efficiencies, as well as improves the quality of your data output. As diagrammed below, ePDAT™ is capable of interfacing with peripheral devices for measurement of lung function, blood pressure and blood glucose. Data captured using ePDAT™ is uploaded to Inflamx's database using a secure, encrypted internet or cellular network connection; as safeguard a copy of the data is retained on the actual ePDAT™ tablet. This secure database is then accessible in real-time to sponsors to access blinded data or study metrics. Data management allows for real-time data query and resolution, reducing the time to database lock. This allows for remote study monitoring and effective project management. ePDAT™ is already compatible with marketed software systems utilized by our sponsors. ePDAT™ allows for effective medical monitoring such that adverse event reporting and resolution are rapid and responsive. Compliance is also improved utilizing ePDAT™ such that patient scheduling can be made through ePDAT™ with reminders for patient clinic attendance and dosing. Compliance initiatives can be pushed to the patient via ePDAT™ which improves study involvement.



**Contact Inflamx Research today to discuss your drug development program and how the ePDAT™ system can improve your study efficiencies and outcomes.**

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