



eDiary®

Improve eCOA - ePRO Efficiency and Data Quality with Ethical's eDiary® Technology Platform & GxP Managed Services

For Electronic Patient Reported Outcome choose an All-inclusive Enterprise Software Service and relieve your Clinical Team from all the burdens associated with the software & data management of your Clinical Studies.

Ethical's eDiary Cloud Software Solution provides

- Patients' Data Collection Mobile Apps / Mobile Devices;
- Investigators' Patients Management and Monitoring Mobile Apps / Mobile Devices;
- Cloud Application Database for real-time Tracking & Audit available to Study Staff and Sponsors ;
- Standard / Custom Export of data/metadata (PDF, XML, SAS).

Ethical's eDiary includes all Software related Services

- ISO 27001 Cloud System Hosting & Management (backup/monitoring/security/business continuity);
- Software Validation packages, Stage Environment for Test and Training;
- Protocol based Software Configuration (forms, edit checks, workflows, data exports);
- Mobile Devices delivery, configuration and management;
- Patients, Investigators and Staff training services
- Technical Support through integrate Help Desk

Patient Reported Outcome Software Made Easy

Ethical is not just a technology company; we hold the experience and expertise in clinical trials GxP Data Management to make a difference in your costs and timelines.

Our approach is simple, rapid and effective:

Protocol Evaluation we get your Protocol and develop a software plan / URS for your study.

Software Configuration we implement your approved Study Protocol in the validation clone environment.

UAT and Acceptance you make tests and validation of the software checking all features against the provided URS's.

Production Release & Ongoing Support

we release & keep working the eDiary solution and support you throughout the study, so you can better focus on your goals.

"Using the Ethical eDiary® solution for our Patient Reported Outcomes Study improves the efficiency of the data collected and the quality of our processes, allowing a timely monitoring of the operations. The Online management of Patient Diaries greatly facilitates the work of the Staff, Patients, and Investigators. The software and devices are in fact providing them with all the features required to collect the Patients' Clinical Outcomes in a flexible quality controlled environment"

Salvatore Bellinva , Managing Director, PPM Services





Benefits for Every Function

Ethical's Enterprise eDiary® solution makes eCOA / ePRO easy and seamless by enhancing Patients' data workflows for every stakeholder in the trial process.

Study Leaders and Staff benefit from lower total cost of ownership, strict protocol compliance, and complete management oversight.

Patients and Investigators experience limited training, user friendly interactions, easy access and data submissions, reminders and notifications.

Quality Assurance Managers can access fast validation with validation package, audit trail and SOPs, and a clone central system for UAT and study staff qualification.

Data Managers can easily download structured data and metadata, access SAS/XML configurable export and Integratability, and APIs and integration interfaces.

Three integrated software environments & features

The Patient App and Mobile Devices

Time a Teachlight 19:08 62%

yesterday Diary, Date: 07/7/2016

Number of bowel movements during the day

- As usual
- 1-2 times more than usual
- 3-4 times more than usual
- 5 or more times more than usual

Blood in stools during the day

- No blood in stools
- Traces of blood in stools
- A lot of blood in stools
- Blood only

General well-being during the day

- Generally well
- Fair
- Poor
- Terrible

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The Investigator App and Mobile Devices

380101722 - Visits

Add new visit +

#2 07/18/2016, 4:08 PM Endoscopy: 07/9/2016
Mean score 1: 1
Mean score 2: 2

#1 07/1/2016, 4:04 PM
Mean score 1: 0
Mean score 2: 1

Person Details Data Management

The Central Database: real-time Sites' Status

Country	Site	Active Patients	Site Status	Screening	Treatment	Blocked Patients	Active Warnings
114-Canada	151-LHSC - Victoria Hospital	1	Active	0	1	0	0
804-Ukraine	104-Klavskyi	0	Active	0	0	0	1
826-United Kingdom	103-Jack Jones	24	Active	21	3	0	1
840-USA	102-SMALLSYS INC	6	Active	3	3	2	0
840-USA	653-Center for Advanced Gastroenterology, PLLC	6	Active	5	1	1	2
840-USA	657-IMC, Inc.	2	Active	1	1	0	0
840-USA	659-Cook Children's Medical Center	0	Planned	0	0	0	0

The Central Database: real-time Patients' Status

Patient ID	Visits	Last Visit	Questionnaires	Last Questionnaire	Phase	Patient Status	Active Warnings
950	2	10/10/2016	8	14/10/2016	Treatment	Enabled	False
945	2	09/10/2016	2	08/10/2016	Screening	Enabled	False
945	2	03/10/2016	2	02/10/2016	Screening	Enabled	False
944	0		1	31/08/2016	Screening	Enabled	True
485	2	15/07/2016	3	15/07/2016	Treatment	Enabled	False
487	0		3	12/07/2016	Screening	Enabled	True
486	0		0		Screening	Enabled	False

GxP Compliance

- GAMP 5 Documentation
- 21-CFR Part 11 Compliant
- EU GMP Vol.4 Annex 11
- ISO 27001 Certified

