

# Solutions for Clinical Research



8-2-268/K/12, Navodaya Colony, Road # 2,  
Banjara Hills, Hyderabad - 34, India.  
Ph: +91-40-23545853  
Fax: +91-40-23545882  
e-mail: [sales@indussoftware.com](mailto:sales@indussoftware.com)  
[www.indussoftware.com](http://www.indussoftware.com)  
[www.indus-eoffice.com](http://www.indus-eoffice.com)

Imagination

Knowledge

People

## Solutions for Clinical Research

Indus Business Systems Ltd., since 2002, has been actively working on the solutions required by the Clinical research industry. We have been working for our California based client, which is in partnership with one of the most prestigious universities in the world for the development of the solutions for managing clinical research. These solutions cater to the guidelines stipulated to the Institutional Review Boards (**IRB**) by the FDA and also to the guidelines stipulated to the Institutional Animal Care and Use Committee (**IACUC**) by the US Federal Law and to the **21 CFR** for maintaining electronic records as per the FDA rules. The software is now being customized for some other customers in different business segments like Pharma, Hospitals, Universities etc., and has separate modules for **Human Subjects** and **Animal Subjects**.

In essence the IRB and IACUC systems deal with Protocol Management. Protocol is the detailed plan for conducting a clinical trial. It states the trial's rationale, purpose, drug or vaccine dosages, length of study, routes of administration, who may participate and other aspects of trial design.

### The Features

- Protocol Preparation
- Protocol Submission
- Protocol Review Process, which is complete with Comments Management
- Protocol Approval Process, which is complete with Meetings Management
- Revision Management, which is complete with Version Tracking
- Renewal Management
- Consent Forms (Not Applicable for Animal Subjects)
- Document Attachment at all Stages
- Protocol Status Tracking
- Protocol Printing, the Required Reports Generation
- Protocol Export to PDF Format
- E-Mail Integration

All in all the features cover the entire life-cycle of a protocol and the systems are designed such that the work flows from one stage to another stage without the need from the concerned users to search into the system for the required actions. Indus can use all this domain and system development knowledge in this field that is acquired with **working for more than 250 Man-Months**, for the customers looking at developing solutions for the clinical research. This kind of solutions is required for the research institutes run the business segments of: pharmaceuticals, universities, hospitals, research laboratories, voluntary organizations and defense establishments.

The interested may contact: [sravan@indussoftware.com](mailto:sravan@indussoftware.com)