



## eClinical Base an advanced and easy-to-use EDC system

Translational Research Center for Medical Innovation, a branch of Foundation for Biomedical Research and Innovation at Kobe, has consistently supported startup and management of clinical researches and studies in academia since its foundation in 2003 and has supported 152 researches by April 2012. EDC systems are fully used in order to manage the researches effectively and we have adopted them in 72% of the running researches, which we are planning to raise to 100% in the future. eClinical Base is an EDC system which we developed based on our experience.

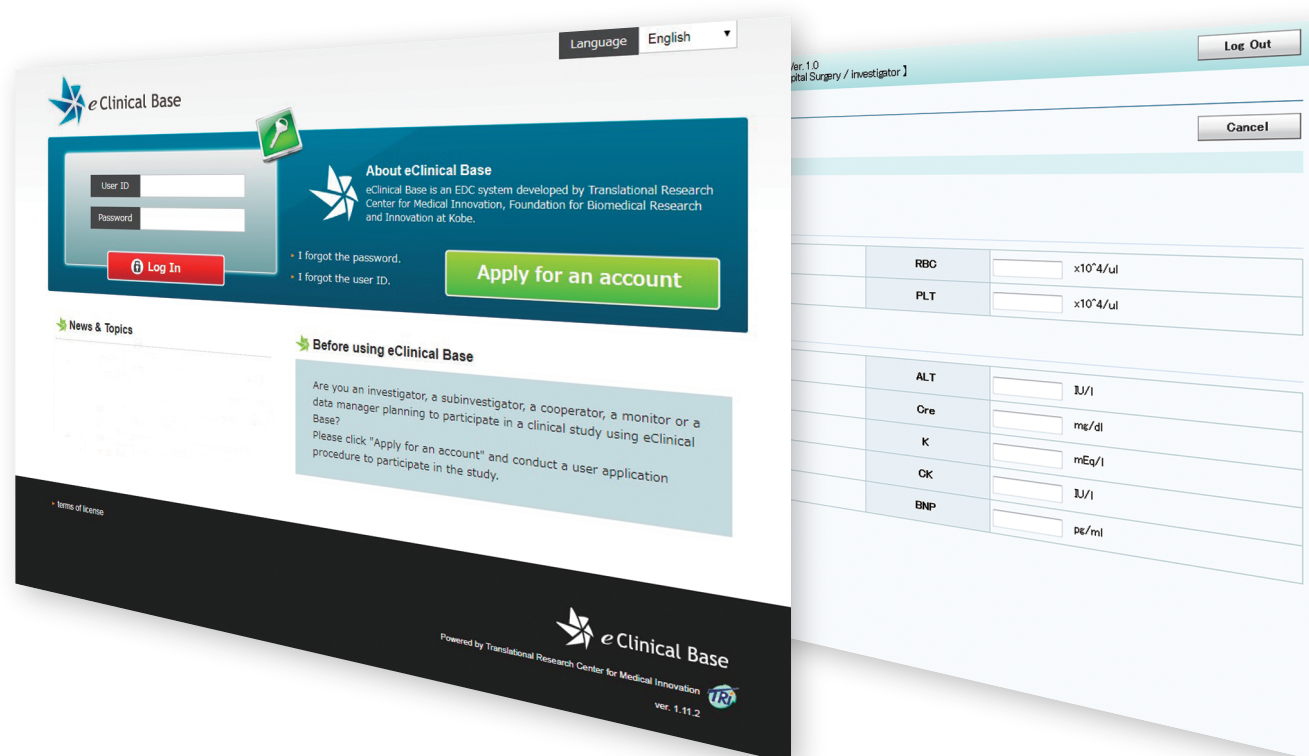
### Features

Import a setting specification document (Excel workbook) into eClinical Base, and the configuration is finished.

- Very easily configurable
- Available for CRF prototyping by data managers
- Specification document completed = EDC study startup completed
- Useful as a tool to standardize test items, variable names, etc. in clinical studies by reusing specification documents
- Audit trail, electronic signature, eCRF, user authority configuration
- Conforms to CFR Part 11, GCP, ER/ES Guidelines

### eClinical Base System Specifications

- ☐ Server Platform  
CentOS / Red Hat Linux and Tomcat
- ☐ Client Requirement  
Web browser and internet / intranet connection
- ☐ Recommended Environment  
Windows -- Windows XP or later and IE 8.0 or later  
Mac OS -- Mac OS X 10.4 Tiger or later and Safari 4.0 or later
- ☐ Database  
MySQL
- ☐ Security  
SSL encryption



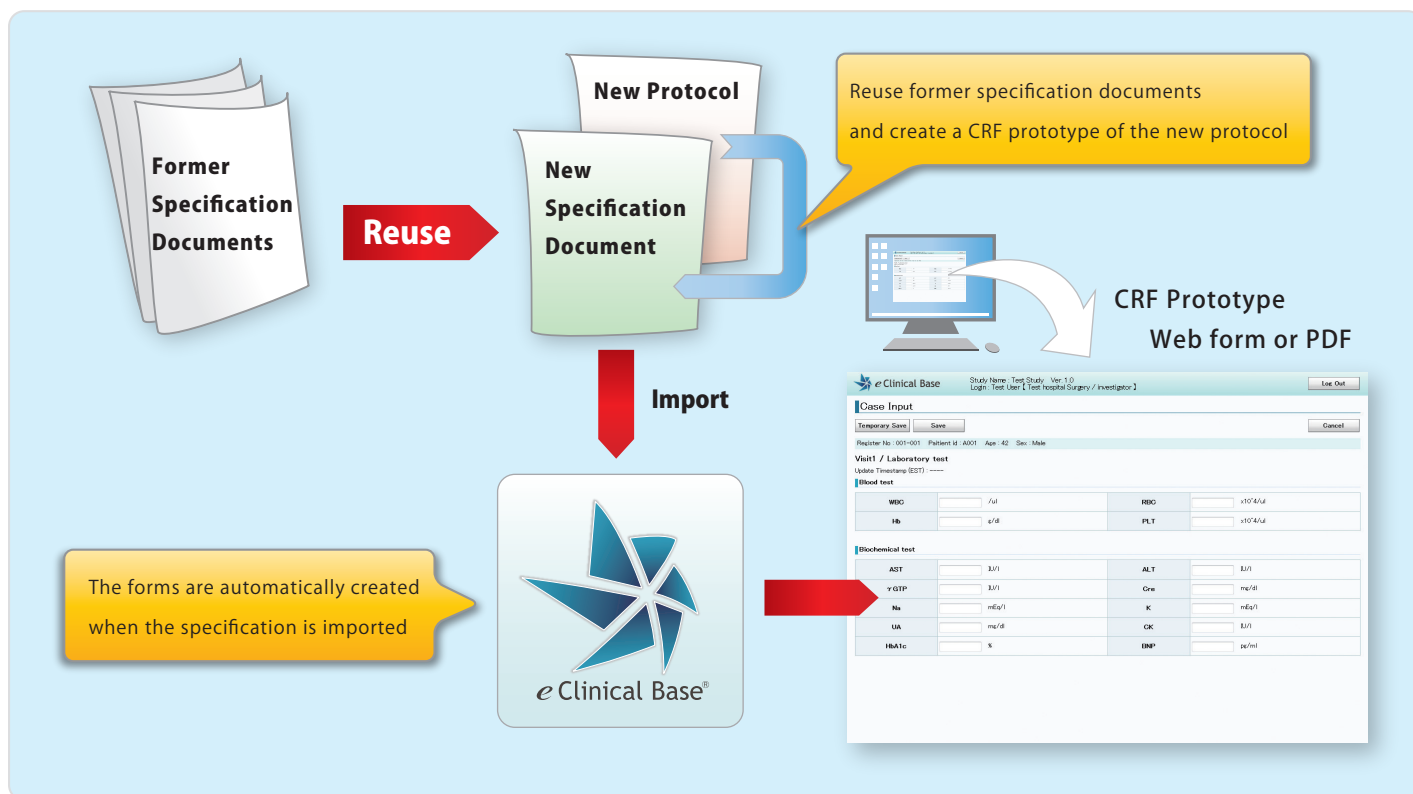
 **Contact** If you have a question about eClinical Base, don't hesitate to contact us.

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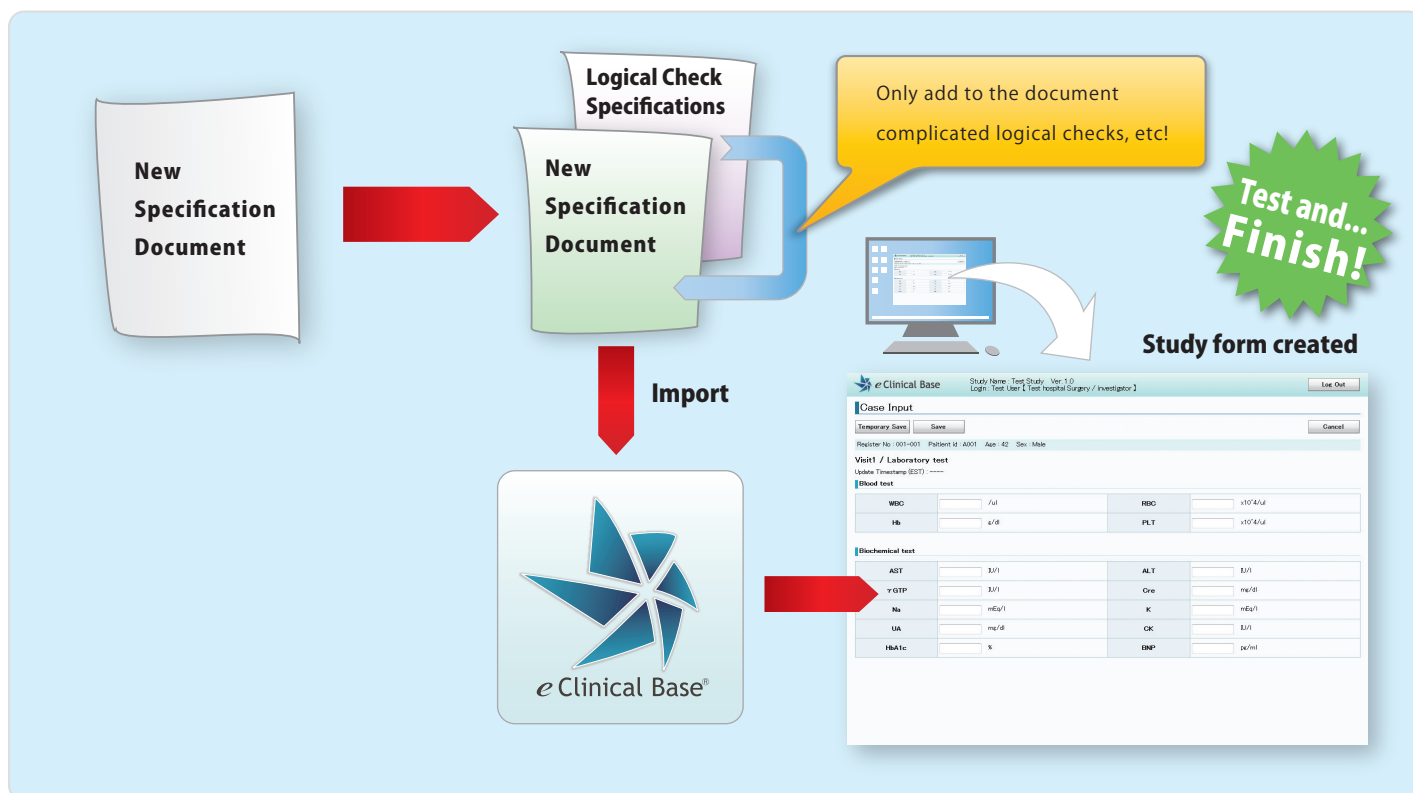


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## 1 Create a CRF prototype The data manager creates a CRF prototype.



## 2 Configure the study The system engineer configures the study based on the CRF prototype and performs tests.



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