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**

- 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

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

**Contact**

+81-78-303-9093  
http://www.tri-kobe.org/service/
1. **Create a CRF prototype**

   The data manager creates a CRF prototype.

   - **Reuse former specification documents** and create a CRF prototype of the new protocol.
   - CRF Prototype Web form or PDF
   - The forms are automatically created when the specification is imported.

2. **Configure the study**

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

   - **Logical Check Specifications**
   - Only add to the document complicated logical checks, etc!

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