

**UMIN**

## University hospital Medical Information Network and its engagement for LibreClinica

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**UMIN UMIN Statistics**

**The Number of Registered Users**

**The Number of Web accesses per month**

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**UMIN What is UMIN?**

One of the largest and most versatile academic network information service for biomedical sciences in the world

with more than **600,000 registered users** and **100 million web pages** per views in a month,

funded by the Japanese government (National University Grants).

Annual budget: About two million dollars  
⇒ Office, computer room, utility expense, and network environment are provided by The University of Tokyo Hospital free of charge.  
The number of full-time staff: 30

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**UMIN UMIN EDC Projects**

INDICE Standard EDC software package was developed by UMIN in 2000 for **complex** research design trials.  
⇒ EDCs of individual trials were programmed by UMIN staff.

INDICE Cloud EDC software package was developed by UMIN in 2017 for **simple** research design trials.  
⇒ EDCs of individual trials are prepared by research groups themselves, using Web-based user interface.

LibreClinica EDC software package is in preparation for **complex** research design trials in stead of INDICE Standard.  
⇒ EDCs individual trials will be prepared by both UMIN staff and **any third parties**.

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**UMIN UMIN Services -Overview**

<p><b>Research</b></p> <ul style="list-style-type: none"> <li>AC Academic societies and meetings database</li> <li>CTR Clinical Trials Registry</li> <li>ELBIS Electronic Library for Biomedical Sciences</li> <li>FIND Fund Information Database</li> <li>INDICE Internet Data and Information Center</li> <li>ROCCLS Recruiting System for Our Colleagues and Students</li> </ul>	<p><b>Education</b></p> <ul style="list-style-type: none"> <li>EPOC Online evaluating system of postgraduate clinical training</li> <li>DEBUT Dental training Evaluation and laBilitation system</li> <li>ARIA</li> <li>VHP Mobile Human Project image data</li> </ul>	<p><b>Multipurpose</b></p> <p><b>Information and database services</b></p> <ul style="list-style-type: none"> <li>Collection of biomedical web sites</li> <li>Medical terms glossary</li> <li>Research institutes and hospitals database</li> </ul> <p><b>Homepage hosting services</b></p> <ul style="list-style-type: none"> <li>Open homepage hosting service</li> <li>Member-only homepage hosting service</li> <li>Academic homepage hosting service</li> <li>VOD hosting service</li> </ul> <p><b>Communication support services</b></p> <ul style="list-style-type: none"> <li>Email service</li> <li>Mailing list service</li> <li>News service</li> <li>BBS service</li> </ul>
<p><b>Clinical practice</b></p> <ul style="list-style-type: none"> <li>Intoxication database (Yamaguchi Univ.)</li> <li>Drug information text database for pharmacists</li> <li>Mailing lists</li> <li>Medical supplies and materials database</li> </ul>	<p><b>University hospitals</b></p> <ul style="list-style-type: none"> <li>Official documents database</li> <li>University hospitals guide</li> <li>Standardized disease nomenclature database</li> <li>Mailing lists</li> <li>Member-only homepages</li> </ul>	

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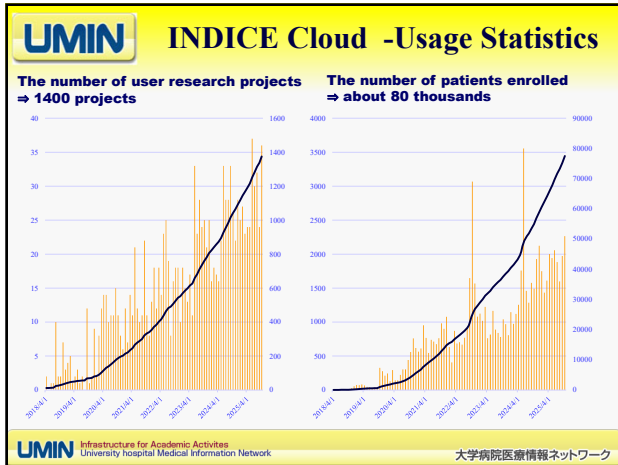
**UMIN INDICE Standard -Usage Statistics**

**The number of user research projects**  
⇒ 256 projects

**The number of patients enrolled**  
⇒ about 10 million

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**UMIN 1. Japanese Localization Summary**

- LibreClinica(OpenClinica) supports localization to any target languages by simply preparing corresponding language message files, collectively called a language pack. No original source code modification are required (built-in feature).
- LibreClinica has no manual language-switching function. The language is switched automatically based on the browser's language settings (built-in feature)
- If all 9 required original English message files are correctly replaced with those in another target language, the target language is used automatically. If one or more message files are missing, the original English language is displayed automatically (built-in feature).
- The Japanese language message files themselves were generated using machine translation.

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**UMIN Engagement of UMIN for LibreClinica**

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**UMIN 1. Japanese localization**  
The 9 message files for multilingual support

File	Lines	Size	Description
words_ja.properties	3,148	157KB	UI labels and captions
page_messages_ja.properties	1,261	129KB	Page messages and descriptions
notes_ja.properties	801	100KB	Notes and discrepancy-related
exceptions_ja.properties	409	33KB	Exceptions and error messages
terms_ja.properties	419	14KB	Term definitions
workflow_ja.properties	331	12KB	Workflow-related
audit_events_ja.properties	273	19KB	Audit log events
format_ja.properties	102	3KB	Date and number formats
admin_ja.properties	100	3KB	Admin screen messages

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**UMIN LibreClinica Modifications**

To promote academic use of LibreClinica, the following features were evaluated and modifications were made accordingly.

1. Japanese localization
2. Random allocation
3. Current Browser Support

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**UMIN 1. Japanese localization Results**

The screenshot shows the LibreClinica web interface with Japanese text, including a header with the UMIN logo and a main content area with various buttons and text elements.

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**UMIN 2. Random allocation**

- LibreClinica and OpenClinica does not have a built-in random allocation function. Thus we developed random allocation function module.
- OpenClinica has some functions to call an external random allocation system. However, current LibreClinica has had these functions removed.

↓

- We developed original external random allocation system, LCRand, in Django (Python) which can be called from OpenClinica.
- We added functions to call an external random allocation system to LibreClinica, modifying those from OpenClinica.

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**UMIN 2. Random allocation Features of LCRand (2/2)**

Category	Details
Randomize Authorization	<ul style="list-style-type: none"> <li>• Supports multiple individual LibreClinica instances (endpoint configuration) Configurable per trial (per LibreClinica instance)</li> </ul>
Concurrency Control	<ul style="list-style-type: none"> <li>• Concurrent Randomizes to the same trial are serialized for processing</li> <li>• Block-method sequence conflicts are prevented</li> <li>• Double consumption of kits is prevented</li> <li>• Can withstand concurrent access from large-scale multi-center collaborative trials</li> </ul>
Randomize Completion	<ul style="list-style-type: none"> <li>• Randomize is finalized when the requester (e.g., LibreClinica) receives the result; if receipt cannot be confirmed, the Randomize is rolled back</li> </ul>
Cryptographic Random Numbers	<ul style="list-style-type: none"> <li>• Cryptographic random numbers compliant with GCP / ICH-E6</li> <li>• Satisfies the unpredictability required by the ICH-E9 statistical guideline and the FDA "Guidance for Industry: Adaptive Design Clinical Trials"</li> </ul>
Logs	<ul style="list-style-type: none"> <li>• All critical operations are logged. Each record includes a SHA-256 chain hash covering all prior records, enabling tamper detection.</li> </ul>
Concurrent Login Prohibited	<ul style="list-style-type: none"> <li>• Concurrent logins with the same account are prohibited</li> </ul>

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**UMIN 2. Random allocation**

- Language and development environment of LCRand

Component	Technology	Version
Web Framework	Django + Django REST Framework	5.2 / 3.x
Language	Python	3.10+
Database (primary)	PostgreSQL	14+
Database (reference)	Oracle (UMIN user DB, read-only)	—
Authentication Platform	Shibboleth SSO (UMIN authentication integration)	3.x
Web Server	Apache + mod_wsgi + mod_shib	2.4
Random Number Generation	os.urandom (SystemRandom)	CSPRNG

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**UMIN Screen Sample (Trial List)**

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**UMIN 2. Random allocation Features of LCRand (1/2)**

Category	Details
Supported Randomization Methods	<ul style="list-style-type: none"> <li>• Simple</li> <li>• Stratified</li> <li>• Permuted block</li> <li>• Permuted block (variable block size)</li> <li>• Dynamic (minimization)</li> </ul>
Limits	<ul style="list-style-type: none"> <li>• Number of arms, randomize factors, and parameters per factor are all unlimited</li> </ul>
Weighting / Tie-break p-value	<ul style="list-style-type: none"> <li>• Weighting configurable per factor</li> <li>• Tie-break p-value configurable for the minimization method (default 0.8)</li> </ul>
Randomize Processing	<ul style="list-style-type: none"> <li>• Automatic generation</li> <li>• Randomize table upload by blinded administrator</li> </ul>
Blinding Support	<ul style="list-style-type: none"> <li>• Returns arm information for open trials</li> <li>• Returns Kit number for blinded trials</li> </ul>
Roles	<ul style="list-style-type: none"> <li>• Global Administrator <ul style="list-style-type: none"> <li>• UMIN office administrators only</li> <li>• Holds Trial Administrator and Blinded Administrator privileges for all trials</li> </ul> </li> <li>• Trial Administrator <ul style="list-style-type: none"> <li>• Configured per trial by the Global Administrator</li> </ul> </li> <li>• Blinded Administrator <ul style="list-style-type: none"> <li>• Configured per trial by the Global Administrator</li> <li>• Cannot be concurrently assigned as Trial Administrator for the same trial</li> </ul> </li> </ul>

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**UMIN Screen Sample (Trial Settings)**

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**UMIN** 3. Current Browser Support Summary

- There were 200 locations of source codes where support for older browsers were directly hard-coded, causing malfunctions, validation errors etc., mainly found in JavaScript.  
⇒ We fixed them in order to support current browsers.
- Some bug fixes inherited from original OpenClinica 3 were found.  
⇒ We also fixed them.

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Kiuchi T, Kaihara S: Automated generation of a World Wide Web-based data entry and check program for medical applications. Computer Methods and Programs in Biomedicine 52:129-138, 1996  
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**UMIN** 3. Current Browser Support Major modifications

Original source	Modified source	Remarks
<meta http-equiv="X-UA-Compatible" content="IE=8" />	<meta http-equiv="X-UA-Compatible" content="IE=edge" />	"IE=edge" instructs IE to use the latest available rendering mode; this meta tag is ignored by Chrome / Firefox / Edge / Safari, so it can be applied without adverse effects.
jQuery 1.9.1	<ul style="list-style-type: none"> <li>• jQuery 3.7.1</li> <li>• jQuery Migrate 3.4.1</li> </ul>	Update for security reasons
attachEvent()	addEventListener()	
<ul style="list-style-type: none"> <li>• IE:document.all[]</li> <li>• Netscape4: document.layers[]</li> </ul>	document.getElementById()	

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**UMIN** LCRand program and patch files we prepared for third parties

- LCRand program file
- The following patch files for LibreClinica were created for third parties. Each Patch can be applied independently and in any orders.
  1. Japanese localization patch
    - Multilingual support does not require program modification, but the Japanese language pack (message files) must be correctly placed.
    - No source code is modified, but Tomcat's automatic redeployment may overwrite the files, so this patch is recommended to be applied last (it can be applied in any order, but applying it earlier may increase manual work).
  2. Random allocation system calling functions patch
  3. Current browser support patch

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