Introduction to LibreClinica

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Workshop „LibreClinica - Datenerfassung in klinischen Studien mit dem Open-Source-EDC-System (basierend auf OpenClinica)" am ~~23.8.2022 auf der~~30.9.2022
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OpenClinica/LibreClinica

❖ OpenClinica/LibreClinica is a web-based CDM and EDC system, typically used for clinical trials, but also for registers and other kinds of studies.

❖ provides the features required to be compliant with Good Clinical Practice (GCP)

From OpenClinica to LibreClinica

❖ OpenClinica® (OC) relased by Akaza/OpenClinica in 2005

❖ with OC4 no community version (OC3 still supported, but the forum disappeared...)

❖ OC3 offers good range of functions and has many users worldwide

❖ to keep alive the work contributed by OpenClinica & community, the LibreClinica project aims to…

LibreClinica - Aims

❖ clean up the build process offering a version that can be built independently of OpenClinica-servers

❖ provide a version that can be built compatible for recent versions of JDK, Tomcat, and PostgreSQL

❖ provide minor releases / subversions for bug fixes

❖ provide a free to use version

❖ improve code quality

❖ improve and extend functionality

❖ generate ideas for next generation EDC system

[libreclinica.org/goals.html]

LibreClinica - Aims

❖ The project is to be open source valueing input from contributors, and at the same time providing a reasonably tested production version.

[libreclinica.org/goals.html]

LibreClinica - Community

- ❖ The project started with volunteers from different background, i. e. academia, clinical research service, IT industry.

- ❖ DKFZ Partner Site Dresden

- ❖ Trial Data Solutions

- ❖ GCP-Service International

- ❖ ReliaTec GmbH

- ❖ Tom Hickerson (former Akaza/OC, now clinCapture)

- ❖ UK Aachen, Institute for Medical Informatics

LibreClinica ≠ ReliaTec

libreclinica.org   reliatec.de

COI: Die ReliaTec GmbH bietet Beratung, Support, Betrieb und Validierung von LibreClinica-Systemen sowie Entwicklungsleistungen an.
COI: ReliaTec offers consultation, support, hosting, and validation of LibreClinica systems as well as software development.

First release

❖ LibreClinica founded early 2019

lots of phone conferences – before COVID19 ;-)

❖ LibreClinica Version 1.0.0, 27.2.2020

❖ update and removal of unused libraries, some bug fixes, all except one (JMesa) build dependencies without OpenClinica servers

❖ small graphical adjustment (LC has its own flavour but looks like OC)

❖ see complete list on librelinica.org/download.html Release Notes

❖ Current version 1.2.0 just released 20-Sep-2022

First release

❖ Tests

To make the quality of LibreClinica transparent, test specifications can be used to validate the software. We also offer test results provided by the LibreClinica community. The validation of a computerized system is an extensive task requiring experience particularly if you operate in a regulated environment (such as GCP, 21 CFR Part 11). You can find assistance on the support page.

❖ [libreclinica.org/documentation/]

Further development

- ❖ LC is conservative – remember our mission statement

  So why bother about a remake?

- ❖ technology is evolving, especially web frameworks

- ❖ monolithic → modular architecture

- ❖ weaknesses in source code

- ❖ interfaces mixture of REST, SOAP, and ???

- ❖ mobile devices, attract new developers

Further development, LC2

❖ When doing a remake, how to enable a painless transition?

for administrators

❖ compatibility on database-level?

❖ provide import of ODM1.3 with OpenClinica extensions

for end users (study assistants, monitors, datamanagers etc.)

❖ keep core elements (like subject matrix, events, CRF-definitions) on GUI level

Further development, LC2

❖ When doing a remake, how to enable a painless transition?

general policy

❖ LC will stay open source and use open source components

Further development, LC2

LC-renew-survey
among active community members, n = 6 out of 7 replied

key result regarding architecture

❖ in general importance of separation of front- and backend highly rated

❖ heterogeneous opinions on which languages/frameworks should be used

❖ high interest to plan a LC backend (REST endpoints)

❖ no crashes & improved logging in common configuration errors