















CLINICAL REGISTRIES, RESEARCH DATABASES: ICT

MULTICENTRIC DATA COLLECTION (TRIALDB2) & CLINICAL DATA WAREHOUSING (CLADE-IS)

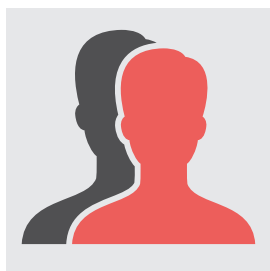
- robust eCRF design
- comprehensive management of user privileges
- easy and ergonomic operation
- proven on thousands of users from the health care sector
- more than 100 live projects covering all medical disciplines

OVERVIEW

ICT INFRASTRUCTURE FOR CLINICAL DATA COLLECTION AND HARMONIZATION IN THE CENTRALIZED DATA WAREHOUSE (CLADE-IS)

- | • Robust eCRF design: | Open schema database | | | | | | | | |
|---|---|---|---|---------|----------|---|--|---|---|
| • Generalized DAM: | Adaptive definition of user roles and privileges | | | | | | | | |
| • Modular approach: | <table border="0"><thead><tr><th>ADMINER</th><th>DESIGNER</th><th>STUDIES</th><th>REPORTER</th></tr></thead><tbody><tr><td></td><td></td><td></td><td></td></tr></tbody></table> | ADMINER | DESIGNER | STUDIES | REPORTER |  |  |  |  |
| ADMINER | DESIGNER | STUDIES | REPORTER | | | | | | |
|  |  |  |  | | | | | | |
| • Easy & ergonomic operation: | Responsive web-design | | | | | | | | |
| • de-Centralization (optional): | Hospital-proxy for personal identity data filtration | | | | | | | | |

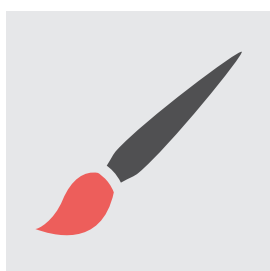
CORE FUNCTIONALITY



ADMINER

Data Access Management (DAM)

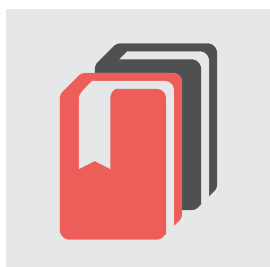
- **configurable privileges**
- **configurable user roles including custom definitions**
SiteCoordinator-Investigator-Monitor-DataManager-MedicalCoder-Admin-...
- **configurable form statuses including custom definitions**
Pending-Complete-Valid-Verified-Signed-Locked-...
- **unlimited hierarchy of regions, institutions, sites, clinics ...**



DESIGNER

electronic Case Report Form design (eCRF)

- **patient forms & site forms**
On-line designer
- **skip logic**
ReadOnly-Disabled-Skipped fields
- **data validation**
Instant Form Validation Rules: mandatory fields – syntax controller – intervals
Complex Validation Rules: data integrity checking
- **calculations**
Computed Values – Events
- **interactive user & clinical guide**
ToolTips – LinkedDocs
- **high customization**
Languages
Layouts – Styles – Logotypes



STUDIES

Web-responsive user interface (UI)

- **dashboard**
Recently Edited Records – HelpDesk Messaging – Queries to solve
- **search engine**
Configurable Parameters & Logic
2-level Results: (i) patients, (ii) forms
- **monitoring & audit trail**
System & Manual Queries
Question-based & Form-based & Phase-based Queries



REPORTER

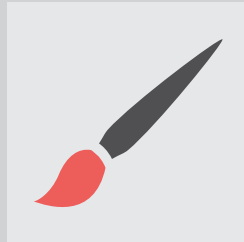
Operational reporting

- **pre-defined reports**
Enrollment – DataCompletion
- **custom report & export definitions**
- **rich formatting capabilities**
XLSx-PDF-HTML5
- **queue processing**
LoadBalancing – E-mailing

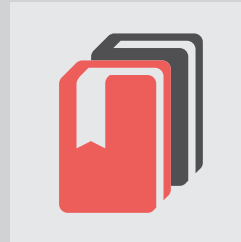
OPTIONAL MODULES



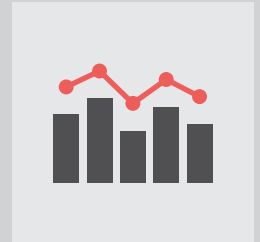
ADMINER



DESIGNER



STUDIES

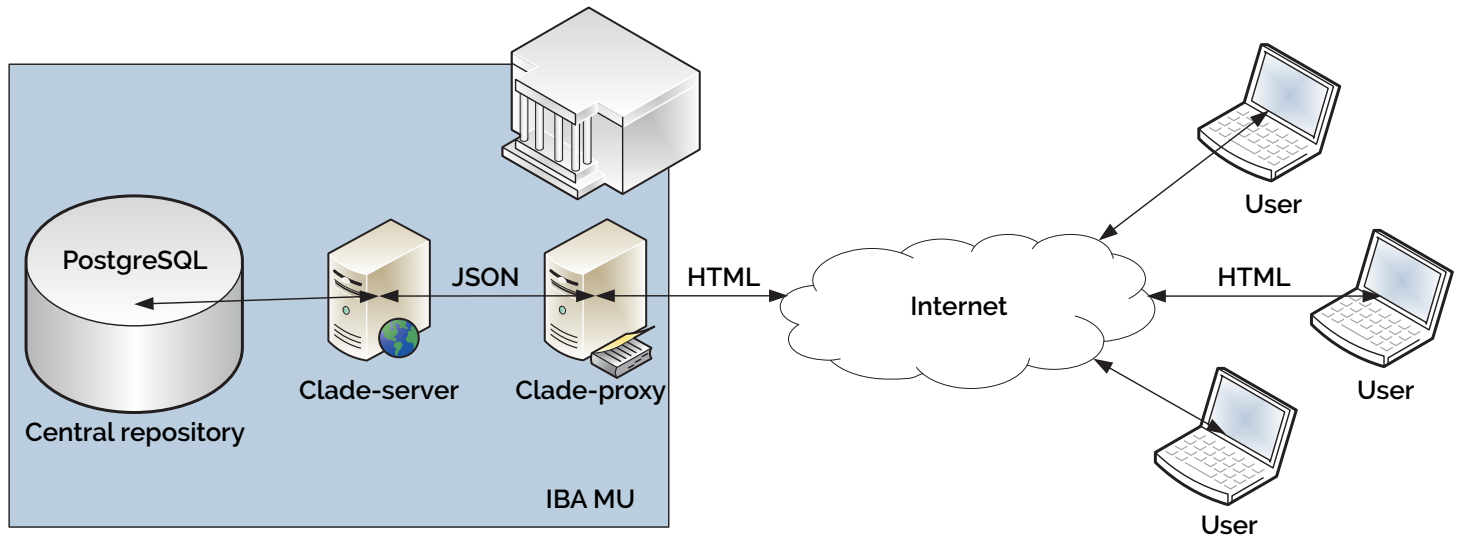


REPORTER

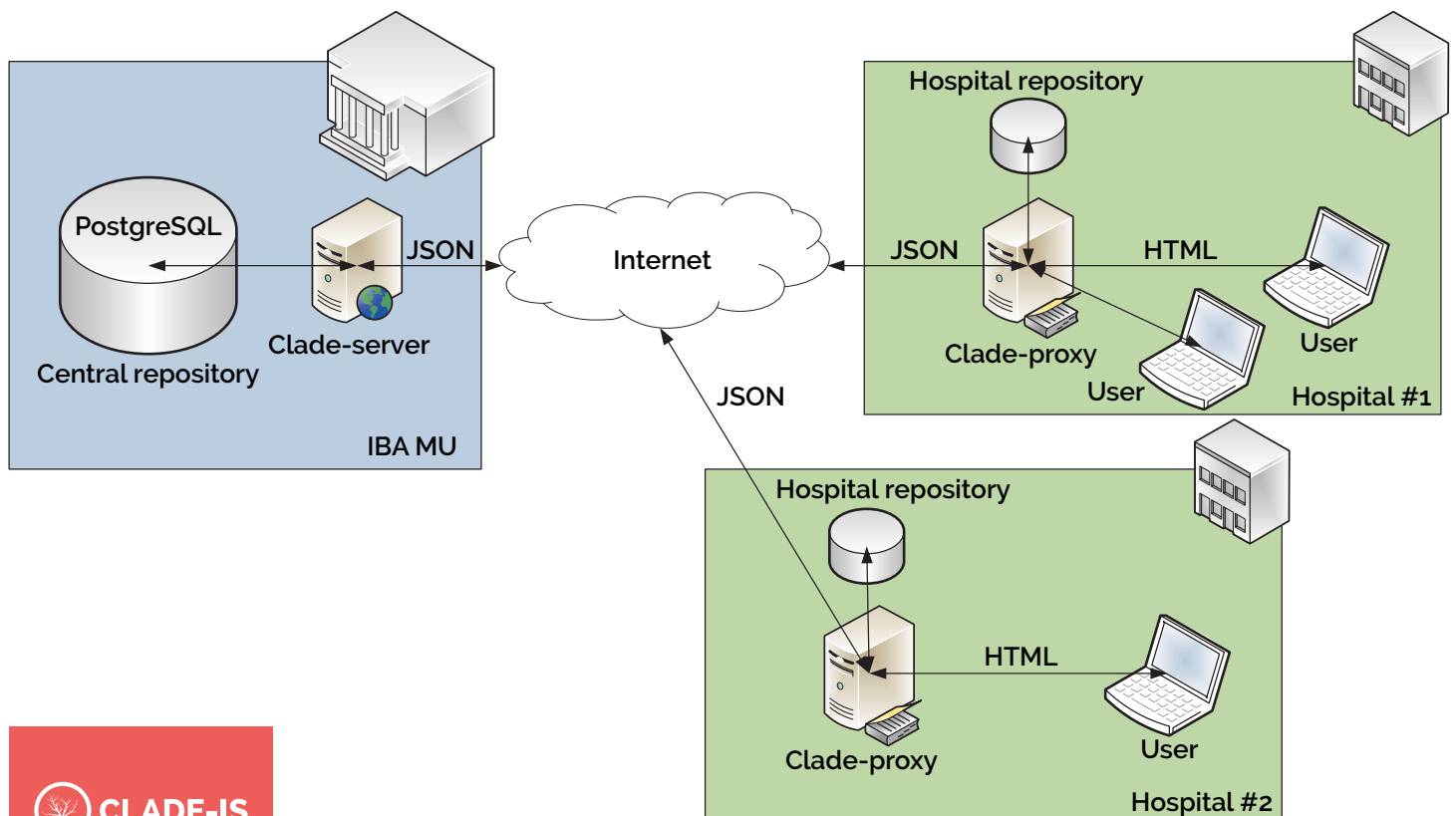
Enhanced functionality

- **application interface (API)**
Integration with external systems – Interoperability
- **external data sources support**
Use of Data From Patients' Devices – Use of Data From Percentile/Risk Tables
- **pharmacovigilance**
Custom Rules and Events – Emailing – PDF reports
- **randomization**
Custom Definitions of Stratification Factors
- **images**
Image-based Questions & Answers in eCRF
- **data & visual analytics**
Integration with R package: advanced calculations
Customized Interactive Data Browsers & DataDriven Documents
Compliance/Adherence Graphical Outputs: integrated in eCRF

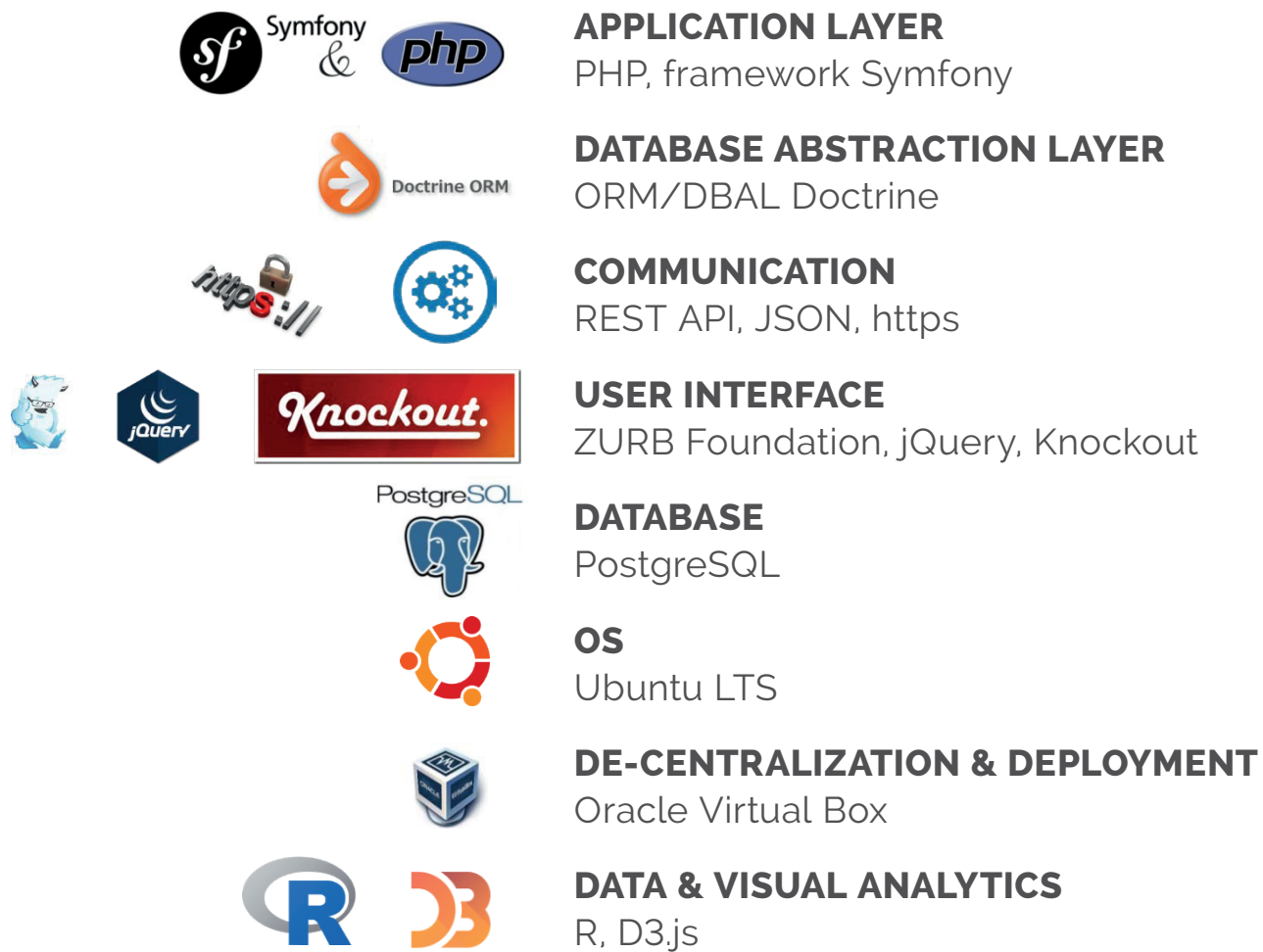
STRUCTURE OF THE SYSTEM (CENTRALIZED)



STRUCTURE OF THE SYSTEM (DISTRIBUTED)



TECHNOLOGY MIX



THE MOST RECENT STABLE VERSIONS OF ALL INCLUDED PACKAGES ARE USED. NO ADDITIONAL PROPRIETARY SOFTWARE LICENSES ARE NEEDED.

DATA SECURITY AND PROTECTION

Physical security



Authorized access



Data backup procedures



Implementation

- training
- data security & protection
- remote administration & management support



CLADE-IS
CLINICAL DATAWAREHOUSE

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