

# DARQA and KOLAB

*Or how a quality assurance group helps open source to make inroads in pharma and healthcare*



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**RMLL / LSM**



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# Who am I?



- OpenNovations
  - Partner of Kolab Systems AG
- Affiliations:
  - Chairman ICT Committee DARQA
  - Knowledge partner Center for Information security and Privacy, ENISA, CYSPA
- Project lead for openSUSE Conference and Kolab Summit 2015
  - And some other conferences

# DARQA?

- Dutch Association of Research and Quality Assurance officers.
  - Target groups: Pharma, Healthcare, Medical
- Goal of DARQA:
  - Knowledge sharing
  - Advocacy
  - Developing reusable components
    - Like qualification and validation procedures.



DARQA  
the quality improvement network

# DARQA members

- Pharmaceuticals
  - Quality assurance laboratories
  - Research and development
- General healthcare
  - Pharmacies
  - Hospitals
- Quite a broad audience.



# DARQA ICT Committee ambitions

- Teaming up with relevant organizations
  - Forum Standaardisatie
  - Center for Information security and Privacy
  - Health Inspection
- Harmonization
  - Investing in creating reusable resources
    - Validation checklists, etc.
  - Reference platforms / applications
- Procurement guidelines
  - Knowledge sharing on how to “acquire” open source.



# DARQA ICT Committee ambitions

- Knowledge sharing
  - What is open source?
    - How does this benefit healthcare? Transparency, etc.
  - How to perform a vendor audit on a hosting provider / cloud service?
  - Introduction in “modern” ICT development strategies
    - Agile, Test Driven Development, Behaviour Driven Development, Scrum



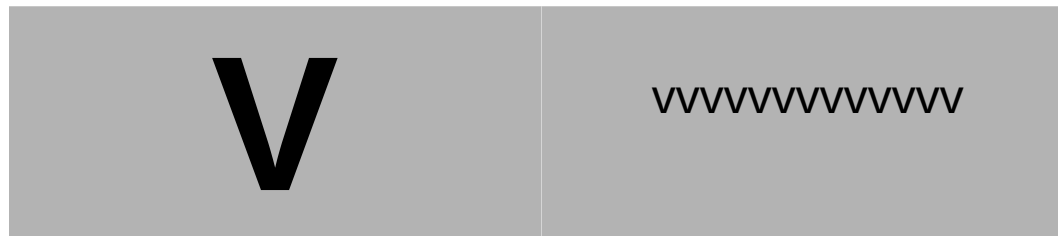
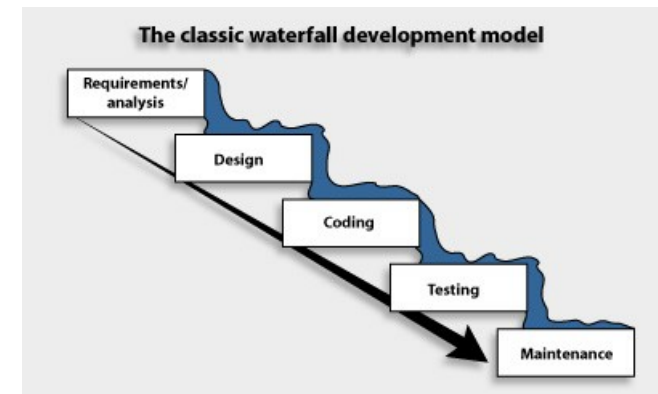
# DARQA and cloud

- “Cloud”, The new kid on the block, most members are sceptical of the compliancy issues
  - Multiple shapes of clouds
    - Internal cloud, public cloud, etc.
- How to perform qualification and validation on a moving target?
  - Risk based approach, GAMP and OSSTMM.
- Open source, open standards and cloud are almost synonymous
  - Need for a cloud strategy
    - Need for an open source strategy



# DARQA ICT Development

- Currently pharma/healthcare ICT development is dominated by waterfall (or V-model)
  - GAMP is very strictly V-model driven.
- But the world is changing, Agile:





# DARQA open source strategy

- “Issues” with open source in healthcare
  - Great quality software, extremely low quality marketing
  - Usually developed from 1 perspective (“scratch an itch”)
    - Research projects, in house development
  - Little to no external qualifications and validations
    - Only for purpose of initial development
    - Open source by definition promotes reusability.



# DARQA Problem with vendor lockin

- Proprietary formats
  - Issues with data sustainability, interoperability
- Mostly occurring in vendor specific device management software
- But also quite often in data/result handling
  - Even spreadsheets (how to validate an Excel document?)



# What will DARQA do?

- Initial qualification, fit for purpose
  - In more than 1 context
  - Develop a library of reference open source applications per domain
- Develop generic checklists and documents
  - Computerized systems validation (GAMP)
  - Cfr 21 Part 11
    - Electronic signatures
- These documents are also reusable for other projects and organizations



Connecting a World of  
Pharmaceutical Knowledge

# DARQA Areas of interest

- Communication and collaboration
  - Exchanging (device) results and communicating about data
  - Inter person communication
  - Team management (tasks, agenda, documents, etc)
- Managing laboratory / test / clinical trials information
  - Storage and archiving of those results
    - Including metadata and securing file integrity
  - Enabling searchability of data
- Information/knowledge management
  - E Learning



# DARQA is looking for projects/partners

- Earlier 2015 co-organization of healthcare track at Kolab Summit in The Hague
  - Projects that participated
    - DHIS2
    - OpenTele
    - MDD Certified applications
      - Medical Device Directive (FDA)
- Follow up at Med-e-tel and other conferences.
- Ideas/projects are welcome!

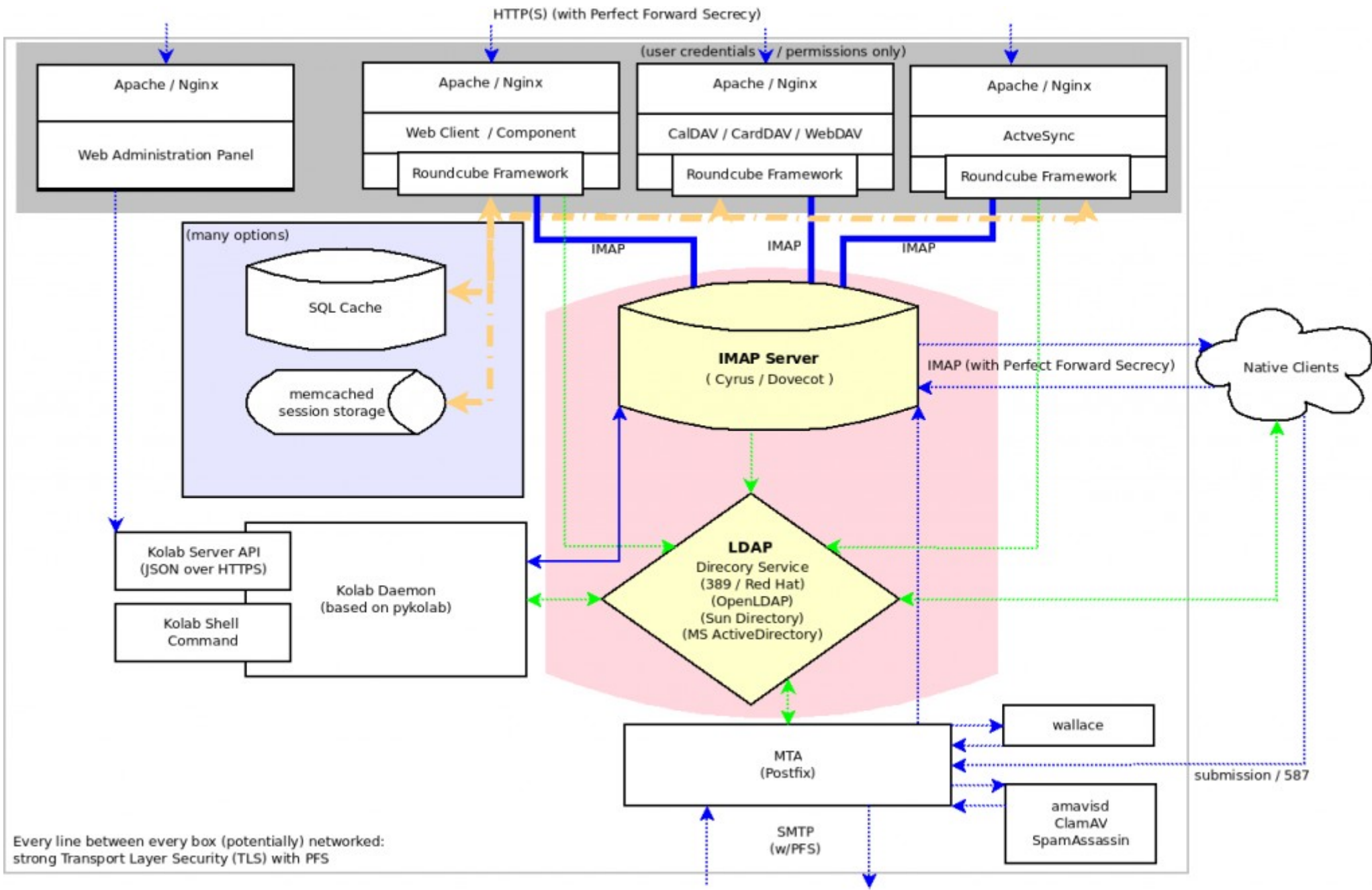


# How does Kolab fit into this picture?

- Kolab Groupware solution
  - Email, calendar, todo management, filestorage, etc, etc.
    - Filestorage is like a controlled “Dropbox” alternative
- Initially developed by German BSI for internal usage
  - Open sourced and now in use by many organizations world wide.
  - Excellent track record on data security and privacy.
- Auditability of components is very finegrained
  - Kolab Data loss prevention is in fact very advanced versioning and action logging.
- Ability of organizations to host in their own datacenter, under their own control

KOLAB

COLLABORATE IN CONFIDENCE



# Usage in healthcare?

- Very important to be able to prove integrity and authenticity of message and message sender
  - PGP and S/MIME
- Data storage must be extremely reliable and any operations on data must be logged
  - The Data Loss Prevention / eDiscovery from Kolab does exactly that for other strongly regulated environments
    - Legal, finance, government
- Offers several very scalable components to use both for internal and external communications
  - With ability to restrict access / communication based on IMAP ACL's.





# Where to go from here?

- Q3 and Q4 2015, DARQA starts development of generic checklists and qualification documents
  - Looking for partners (open source projects) to team up with
- Striving to present a coherent open source healthcare information system proposition on Med-e-tel 2016



# Questions?



# Contact

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