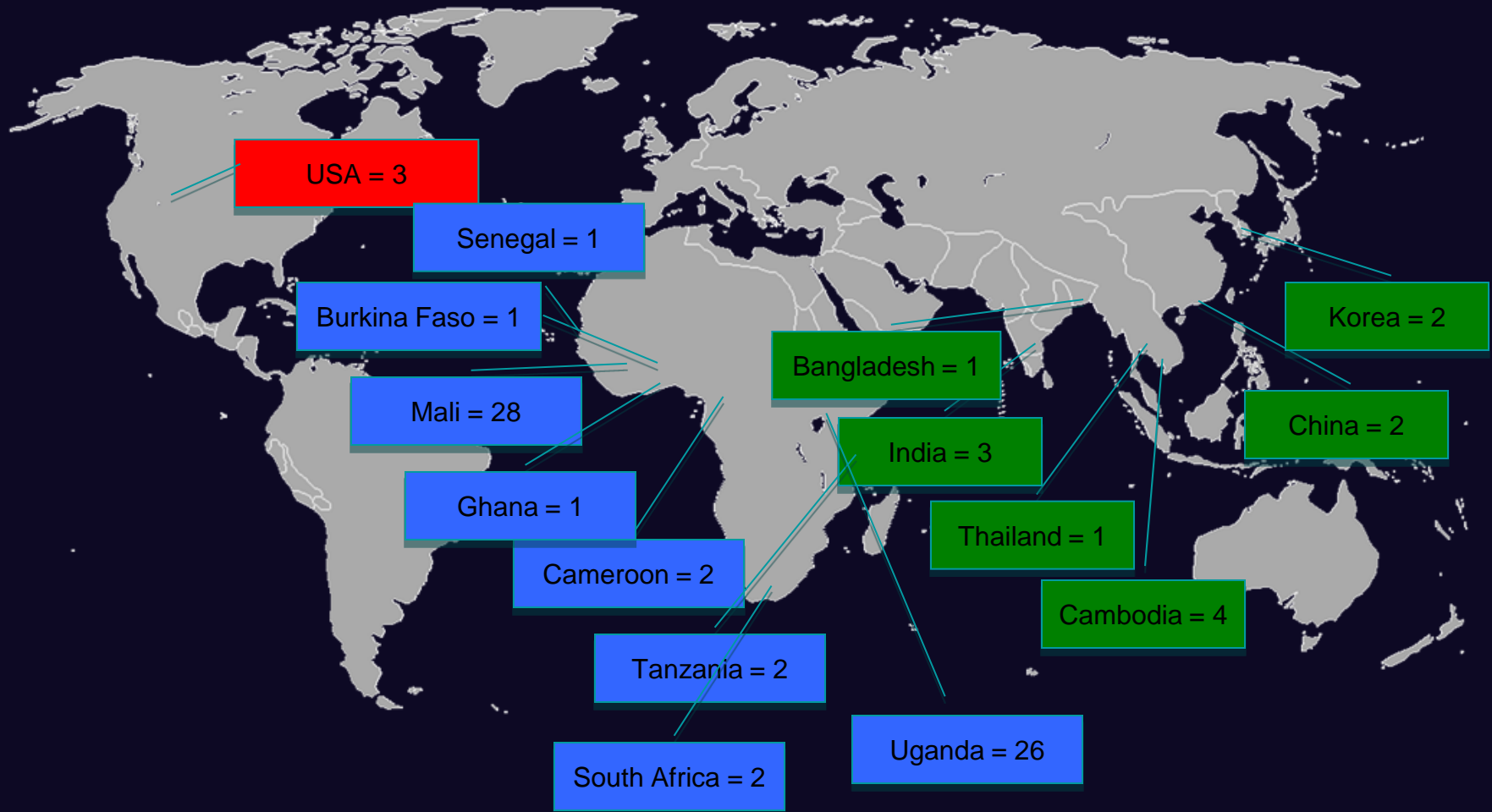

DataFax 2014.1.0 Upgrade Methodology and Lessons Learned

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Computational Biology (OCICB)



NIAID DataFax Operational Support Overview 2015



NIAID DataFax Operational Support Overview 2015

Number of Production Studies on DF2

76

Number of Countries

13

Number of Active Users

144

Number of CRF Pages

1,233,629

*Unsuccessful or problematic upgrade to DataFax 2014.1.0
held huge risk for the NIAID DataFax Operations*

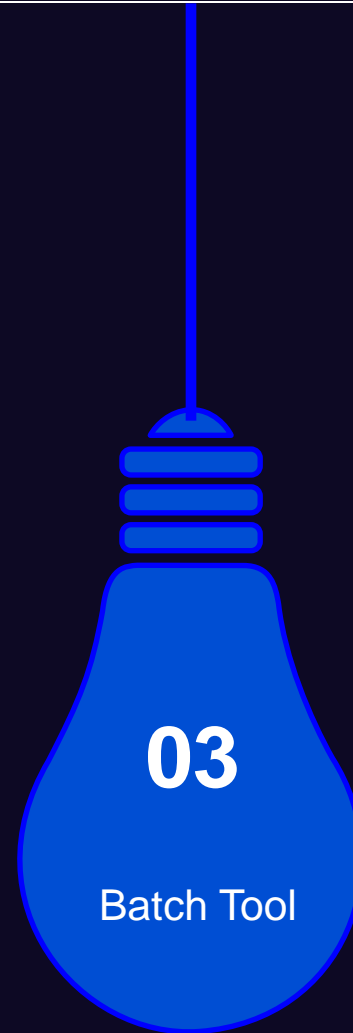
Primary Upgrade Reasons



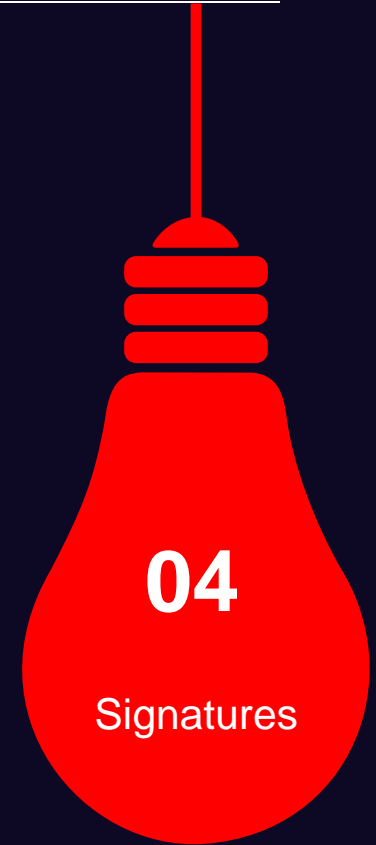
01
Modularization of plates and items (CDISC compliance); better ability to view data across plates



02
DataFax now uses protocol TLS instead of SSLv3.0 due to security vulnerabilities



03
Ability to use the Batch tool operations directly from the Client tool

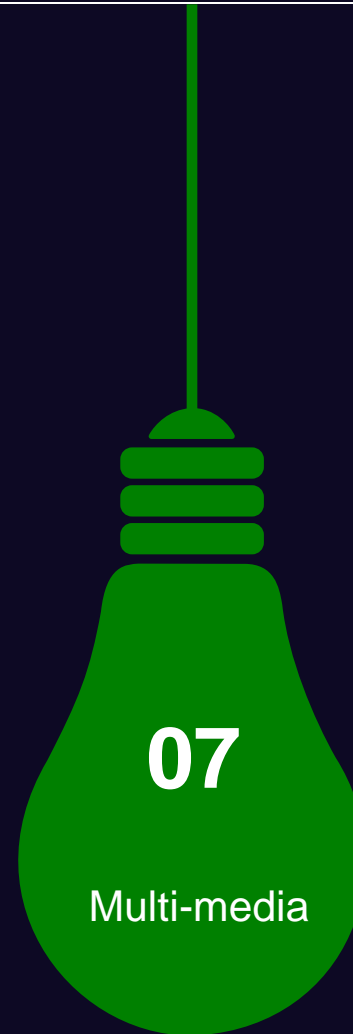


04
21 CFR Part 11 compliant e-signature module was added

Primary Upgrade Reasons (continued)



06
CDISC ODM export has
been added further
allowing CDISC
compliance



07
Multimedia files (PDFs, DICOM
images, audio, video) to be
attached to patient records

Risks Management

- Cost-shifting role of setup primarily to internal team (away from experienced NIH Data Managers)
- Training users: internal team, NIH DMs, international site contacts (iDF + DFSetup aspects)
- Internal learning curve especially with regard to known factors such as: applying modules intelligently, edit check programming syntax changes for module references; using batch from client tool; reconfiguring other tools such as new syntax requirement for DFbatch
- Reconfiguring of time fields
- Storage impact switching to PNG – additional 10-fold growth in ongoing disk usage

Upgrade Methodology – 3 Phase Approach

- **Dev Server** – Functionality testing; functionality orientation/understanding; training development
- **QA Server** – Planning of upgrade methodology; official testing and documentation
- **Prod Server** – Official upgrade, validation and documentation on production server

Upgrade Methodology – QA Server



02
Upgrade to DataFax 2014.1.0 on QA server

04
Review DFmigrate log; documenting issues; development of roadmap

06
Perform Full-ATK

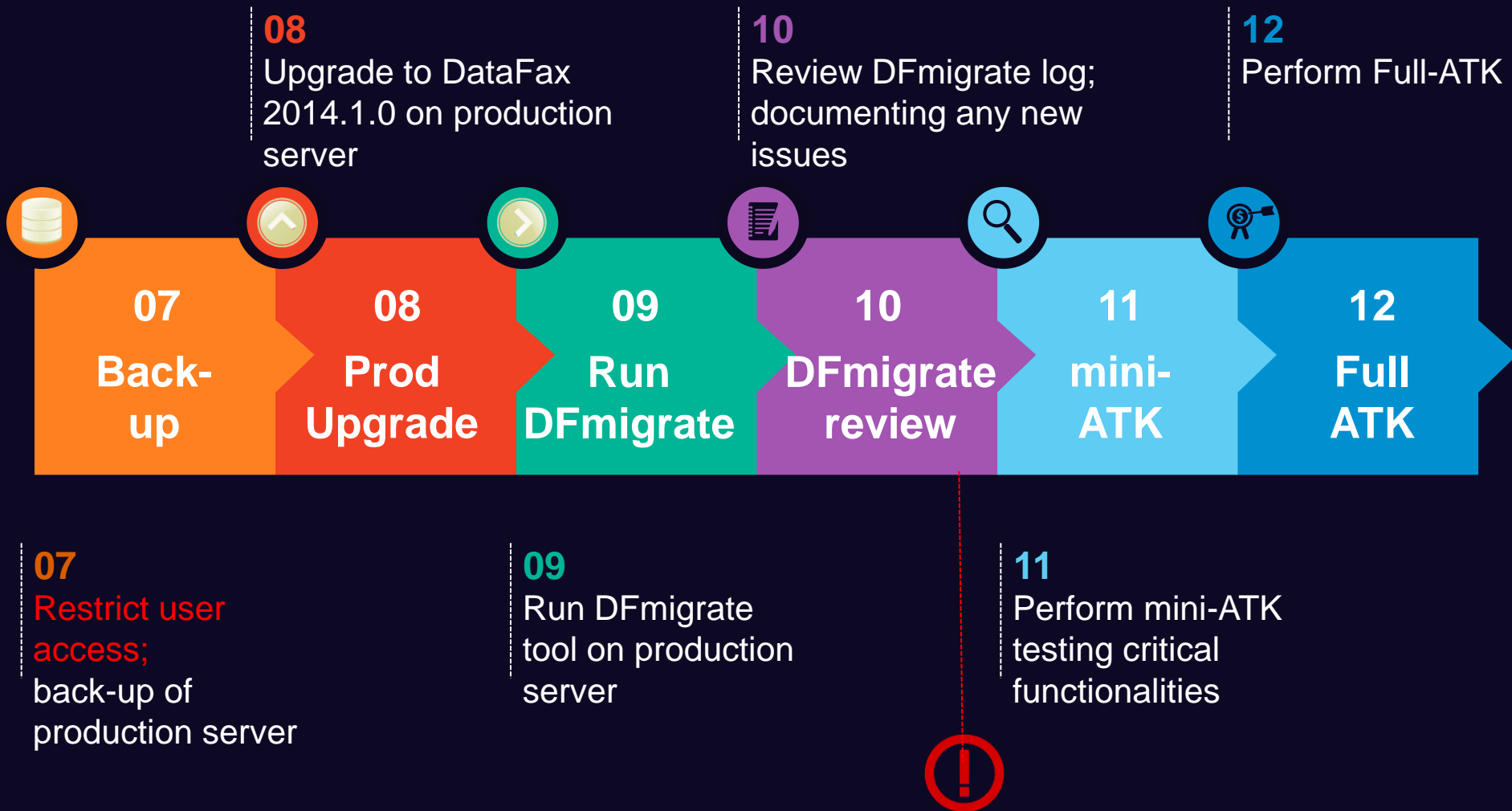
01
Clone Production server to QA server - using the NetAPP storage & VMWare environments (segregated and controlled testing environment)

03
Run DFmigrate tool on QA server

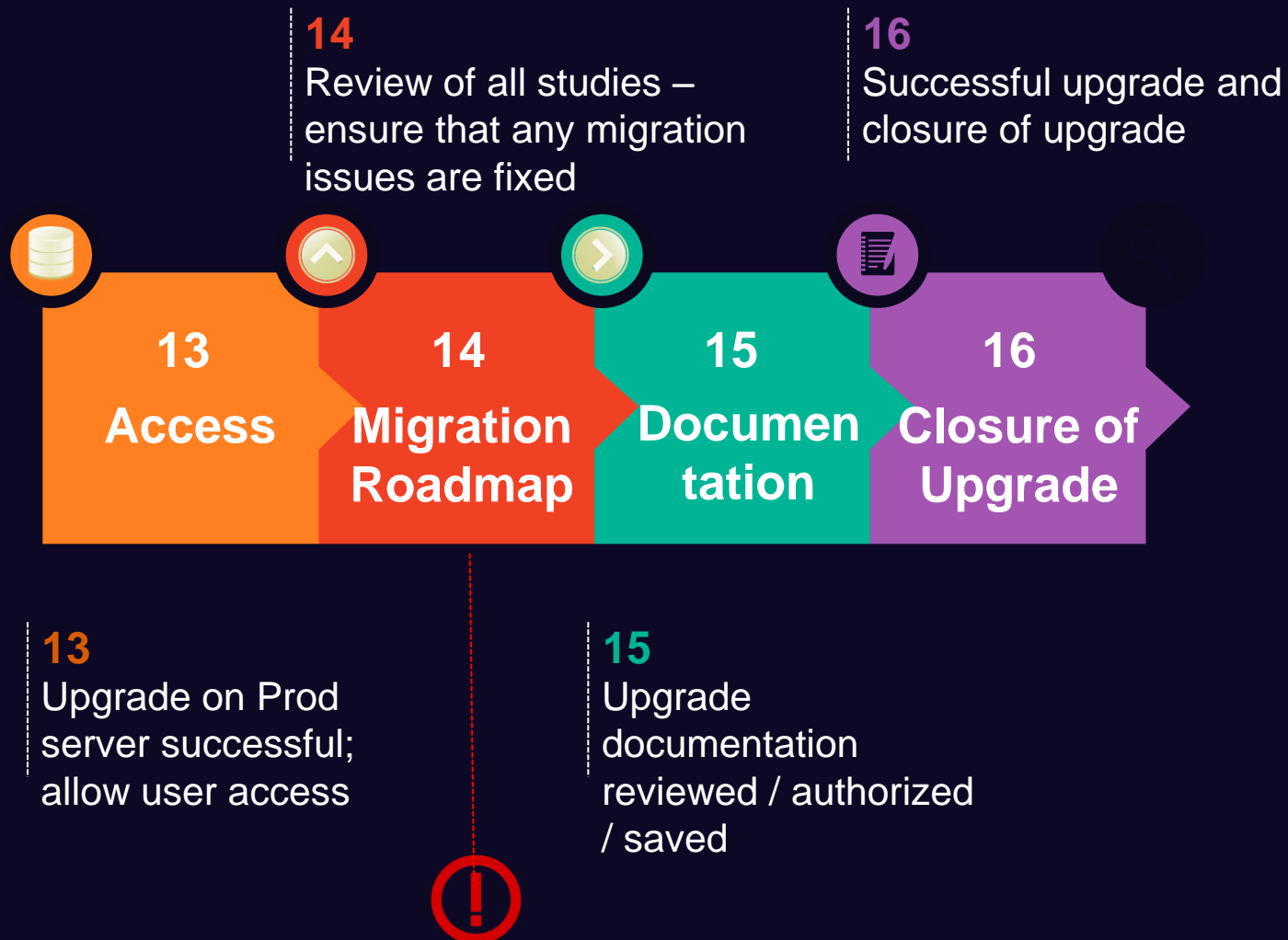
05
Perform mini-ATK testing critical functionalities



Upgrade Methodology – Prod Server



Upgrade Methodology – Prod Server (continued)



Development of the DFmigrate “Road Map”

- Reviewed all studies – Setup State
- Lengthy output to wade through!!!
- Could not fix the Setup State on the QA server – had to be fixed on the production server (during “official” upgrade)
- Limited time during official upgrade, so needed an exact “road map” of where to correct setup issues

Most Common DFmigrate Issues

- Meta-words used on 'Name' removed
- Format contains invalid characters for numeric field, e.g. nn:nn for numeric time
- Invalid length for numeric field (Max: 10)
- Other setup warnings/errors that were previously not addressed

Why Do a Mini-ATK?

- Reduced ATK developed specifically to focus on a reduced set of critical DataFax functionalities
- Utilized as a “go/no-go” decision maker for the full-ATK (spot early-on issues)
- It also covers some tests currently not contained in the full-ATK, e.g.
 - DFimport.rpc for electronic mSource data
 - CRF page submissions via email
 - Functionality of Python scripts

Upgrade Timeline

- Dev Server – 2 Months
- QA Server – 1 Month
- Prod Server – 2 Days (Thursday & Friday, with the possibility to extend over weekend if necessary)

Interesting to note was that the DataFax 4.3 upgrade was performed in Oct 2014; DataFax 2014.1.0 upgrade was performed in Jun 2015. Only 8-month period between 2 upgrades.

Upgrade Documentation

- Mini-ATK documentation as performed on QA server as well as production server
- Full ATK documentation as performed on QA server and production server
- DFmigrate log review and corrections as implemented on the production server

Upgrade Challenges

- Development of the DFmigrate log road map (had to be performed across all projects)
- Transform to Time Style for all studies
- What to do about store length warning and format errors for numeric fields?
- Bugs in DFSetup change logs
- Forgot to update DFbatch commands in cron
- Storage: impact of PNG is serious ~ 10-fold
- Licensing challenges (needed 3 server licenses instead of our usual 2)

Summary

- Many advantages to new features available in DataFax 2014.1.0
- Learning curve in stepping into new module framework – best practices in development
- Excellent user support from vendor
- Excellent responsiveness to user requests from vendor

Acknowledgements

- Kevin Newell (RDCT) – DataFax 2014 Upgrade Project Manager
- Michael Holdsworth, Bruce Burgess, Michael Duvenhage, Jiwen Sun – DataFax 2014 Upgrade Core Team
- NIAID OEB Enterprise Storage Team
- NIAID OEB Linux Hosting Team
- NIAID International Clinical Data Support Team

Q&A
