

Future Challenges We Cannot Deny

E-Data Readability, Exchangeability

EBF Open Symposium, 17 Nov 2017

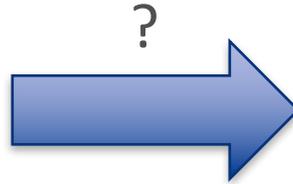
David Van Bedaf, Quality and Compliance Manager
Discovery Sciences | Janssen Research & Development, LLC

Art credit: Discovery Sciences, *U2OS osteocarcinoma cells genetically engineered to fluorescently label tubulin (green) and actin (magenta).*

Personal Experience



Personal Experience



Challenges



- Different operating system (iOS - Android)
- Proprietary data formats (iMessage, iTunes, iCloud)
- How am I going to migrate all data?
 - Export Contacts to Excel and import in the new device?
 - Print out on paper and manually enter the data?
 - Music, photo's, favorites, calendars, ... ?
- Copies of pictures, fresh back-up on iTunes



Solutions



- “Do you want to restore a back-up from another device using the SmartSwitch app?”
- iPhone to Samsung Galaxy
 - Restore from backup on iCloud
 - Restore from backup on PC using iTunes
 - Restore device to device using provided cable
- All data: contacts, photos, appointments, apps, background settings, wifi connections, ...
migrated in 5 minutes !!
- This also works the other way around using the Start-to-IOS app.



How is this possible?

- Did Apple and Samsung – 2 major competitors in Telecom industry – agreed to open their proprietary data formats to each other?
- Are they no longer protecting their Intellectual Property in order not to loose clients?
- They saw commercial benefit in it.
- GDPR (EU approved in 2016) will have played a role: right for data portability
- I was told first to choose the platform (IOS, Android, Windows) and then the smartpone. Stick to your choice.

No longer true today

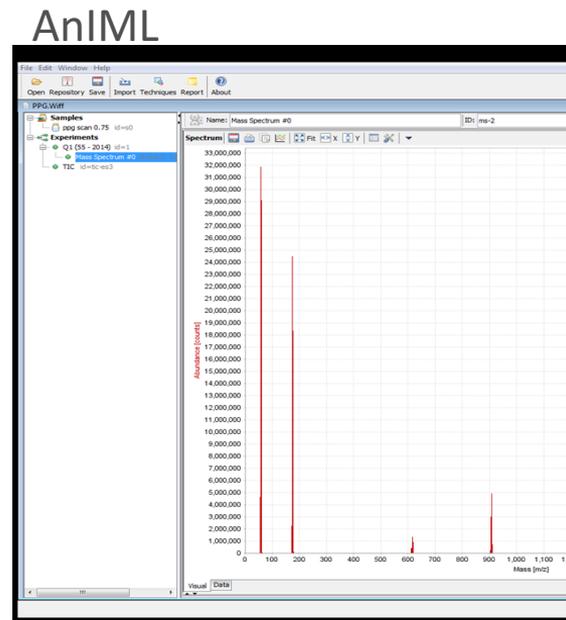
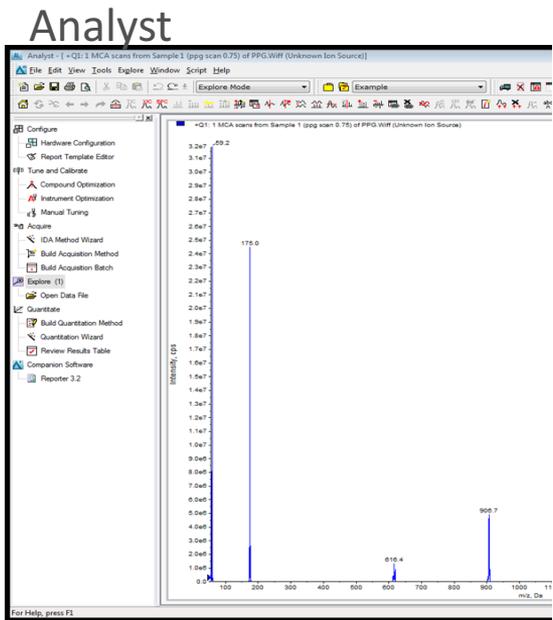
- Data is easily exchangeable between platforms and thus readable longer than my personal retention requirements.
- In Telecom industry exchanging data has become a commodity.

What about us?

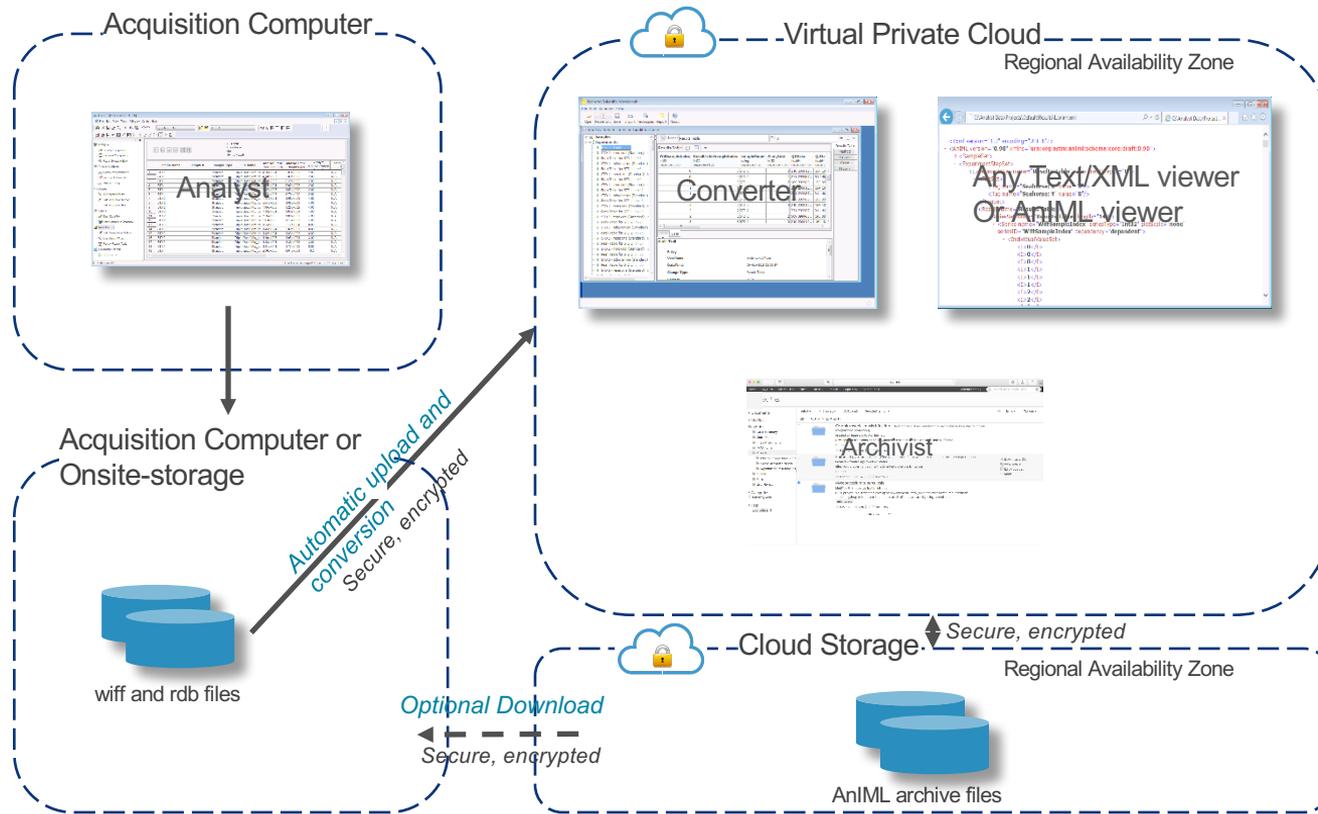
- We all generate and archive e-data
 - We submit study data electronically to FDA in SEND format
- Pharma industry is still very much struggling with
 - Proprietary data formats not shared
 - Exchangeability and readability challenges
 - Legacy data with almost permanent retention schedules
- Pharma is different
 - Highly regulated: OECD, FDA, MHRA, EMA, ...
 - Telecom has to comply with GDPR
 - FDA is requiring to retain data in human readable format since 1997
 - Validate all systems through change controls, documentation, approvals, ...
 - This is also true in Telecom industry
 - QA is making our lives difficult
 - QA is only verifying regulations and procedures
 - Everyone wants quality
- Where is our SmartSwitch app?

Help is on its way

- Sciex Archival Program on Analyst data
- Analyst data converted to the AnIML standard
- Assures long-term readability + reprocessability
- Integration with other systems

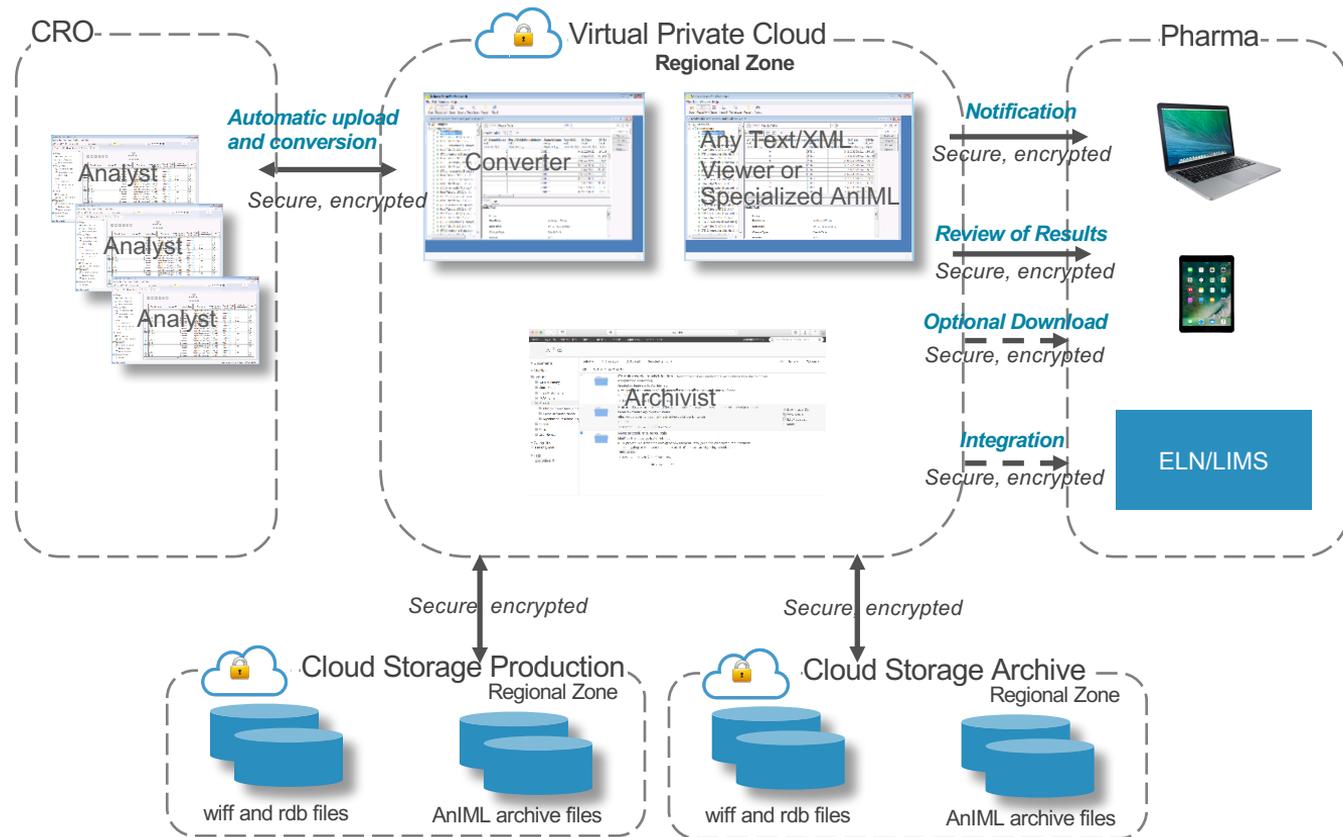


Cloud Solution



With the courtesy of
Sciex

CRO Collaboration



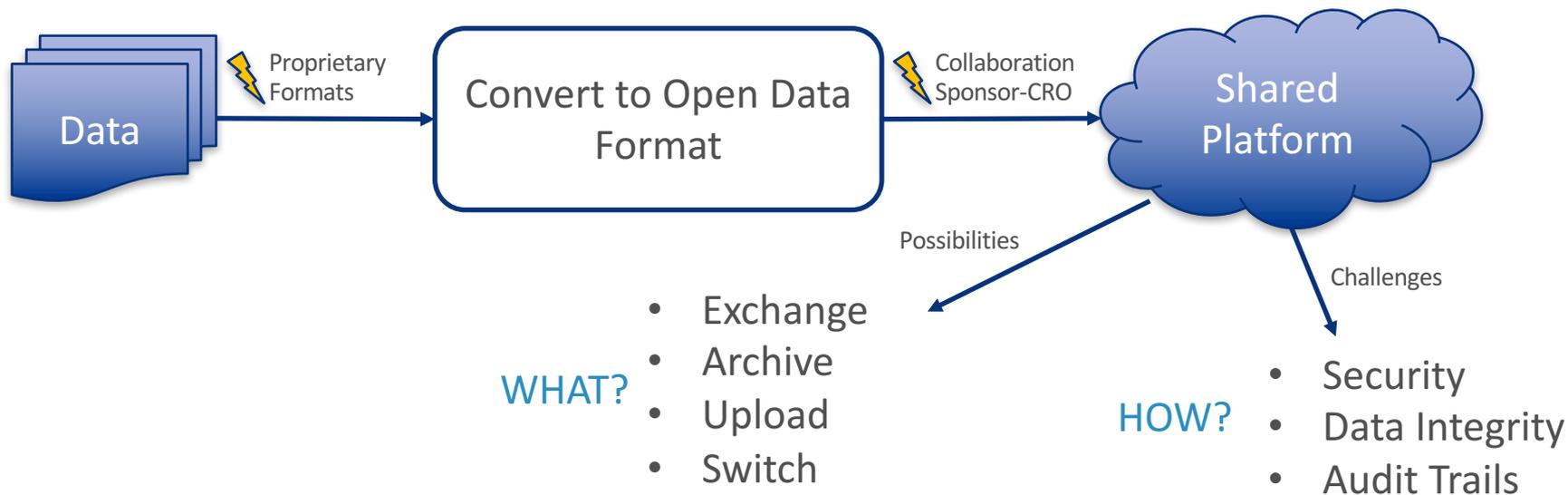
With the courtesy of
Sciex

Features

- Fine-grained permission concept
- Shared folders between organizations
- „Hand over“ functionality to trigger release of data to sponsor
 - Moves data into an inbox on the sponsor side
- „Archivist“ role functionality
 - Moves a project to an archive space
 - Access restricted to archivist
 - Archivist may re-grant access on an as-needed basis
- Distributed audit trails

With the courtesy of
Sciex

New possibilities/challenges



The Time is Now!

Technology is available

Restrict Access, Encrypt Data, Apply Integrity Checksums, XML Apps with Audit Trail

What are the real future e-data challenges?

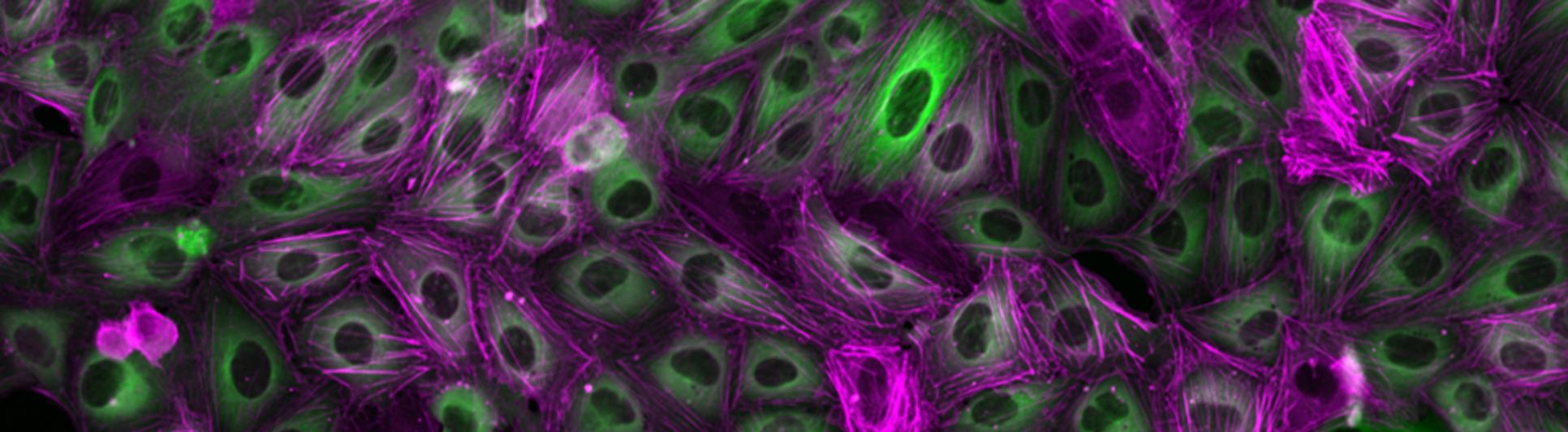
- The Analyst – AnIML use case show vendors are picking up commercial advantages of open data formats.
- Sponsors and CRO's can start thinking what possibilities this brings
 - Data readability
 - Data exchangeability, not only at the end of the project but also during project lifetime
- Imagine what possibilities lay ahead if all analytical data is stored in open data formats and shared on cloud platforms.
 - Not only sharing summary reports
 - Discussing results or acquisition problems, start collaborating in a real time mode
- All kinds of security, privacy and data integrity measures will be necessary
 - Data should only be made available to the correct customer (2 factor authentication)
 - Transfers must be encrypted
 - Version controlled
 - Audit trail enabled throughout all steps
- Technology is available

What are the real future e-data challenges?

- The Analyst – AnIML use case show vendors are picking up commercial advantages of open data formats.
- Sponsors and CRO's can start thinking what possibilities this brings
 - Data readability
 - Data exchangeability, not only at the end of the project but also during project lifetime
- **Imagine** what possibilities lay ahead if all analytical data is stored in open data formats and shared on cloud platforms.
 - Not only sharing summary reports
 - Discussing results or acquisition problems, start collaborating in a real time mode
- All kinds of security, privacy and data integrity measures will be necessary
 - Data should only be made available to the correct customer (2 factor authentication)
 - Transfers must be encrypted
 - Version controlled
 - Audit trail enabled throughout all steps
- Technology is available

Summary

- Proprietary Data Formats are still very much in use and will not disappear
 - Protect intellectual property
 - Better performance, calculations
- Telecom industry shows that opening up data formats creates commercial benefits as well
 - Customers can easily switch between devices without loss of data
 - Data exchangeability has become a commodity
- Pharma industry – conservative in nature – is somewhat behind, but catching up
 - Analyst to AnIML conversion
 - Allotrope Foundation
- Technology is available. Applying it will bring new possibilities and challenges
 - Real time accessibility of analytical data between Sponsor and CRO
 - What used to be difficult is possible today
 - We can start discussing how to deal with this new situation



Thank you