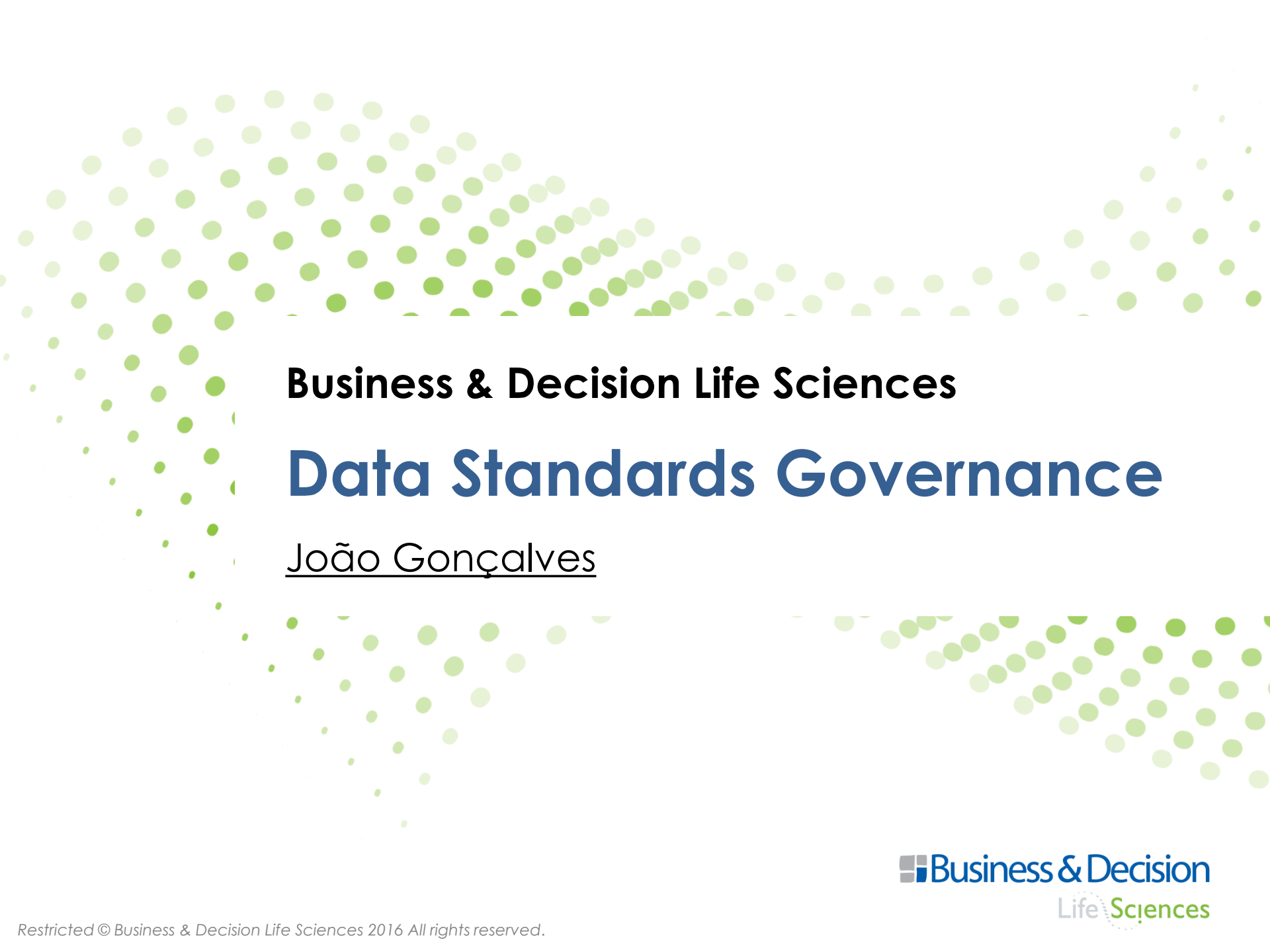


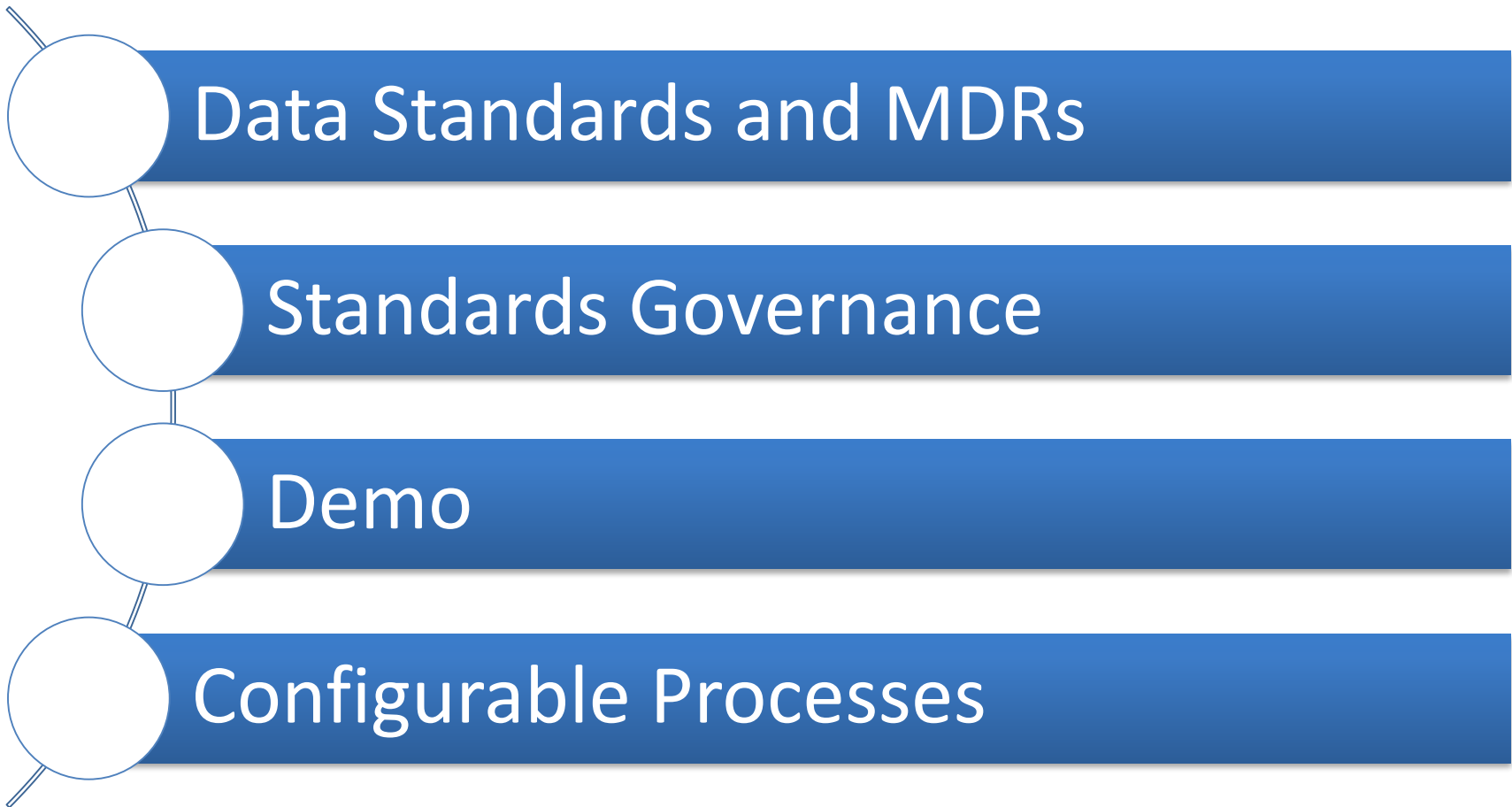


Business & Decision Life Sciences

Data Standards Governance

João Gonçalves

Agenda



Case for Data Standards

- **Submission to regulatory authorities**
 - FDA, EMA, PMDA require submissions following CDISC standards
- **Streamlining data collection and analysis**
 - Enable higher re-use of procedures and code
- **Easing collaboration, both inside and outside organizations**
 - Understood by many, less ambiguous
- **Ease re-use of data in the future**
 - Documentation of standards will persist over time

Case for Metadata Repositories

■ Increasing quantities of standards

- Fast-paced releases of Therapeutic Area standards and controlled terminology

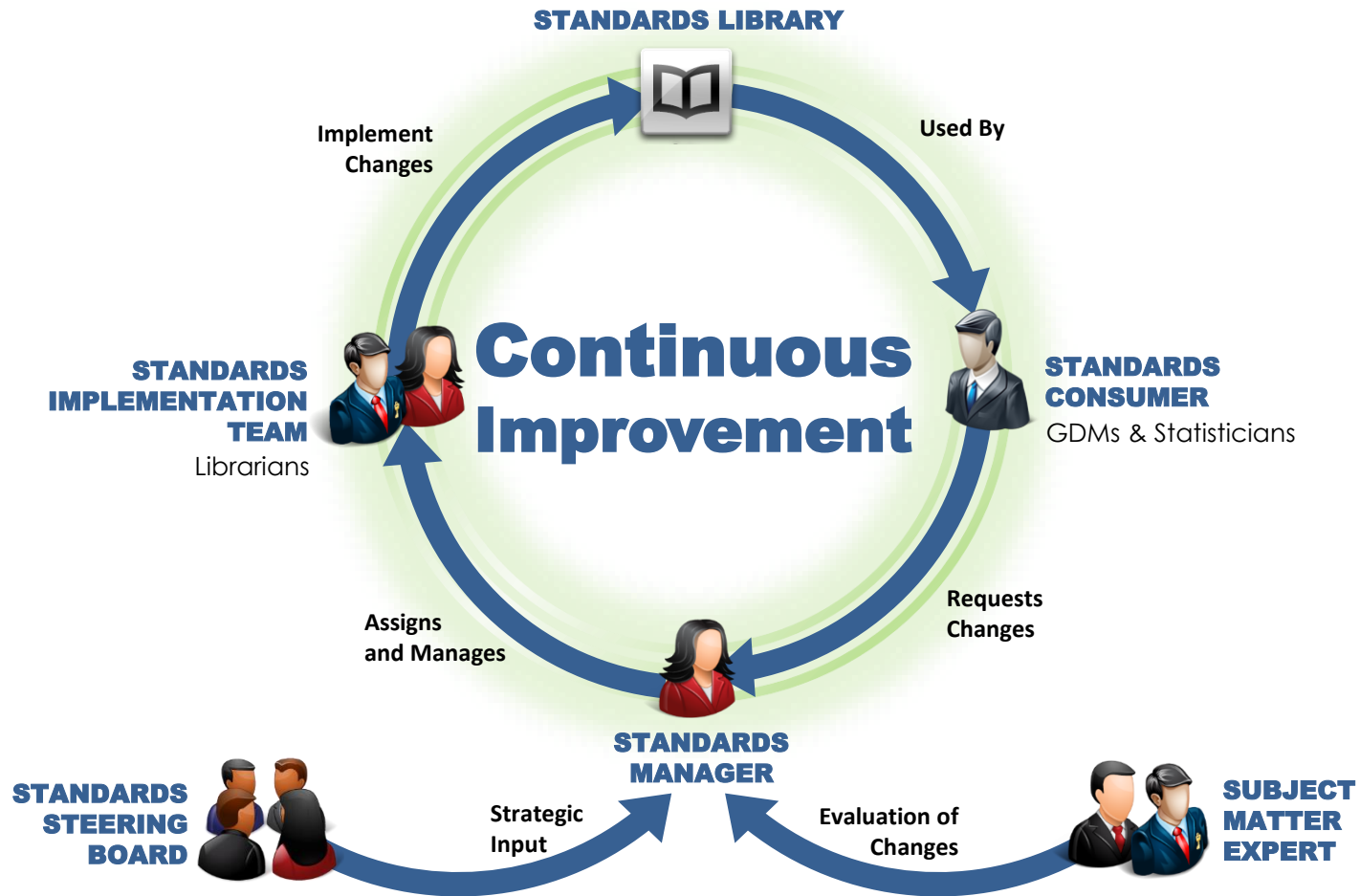
■ Organizations have different standard adoption strategies

- Not all standards and not at release time
- Internal timelines need to be accommodated

■ Adaptation or enrichment of industry standards

- Industry standards are not complete nor the silver bullet
- Organizational flavours are common

Data Standards Governance



Metadata Repositories and Standards Governance

- **Metadata Repositories hold the Standards**
 - Governance process controls MDR content

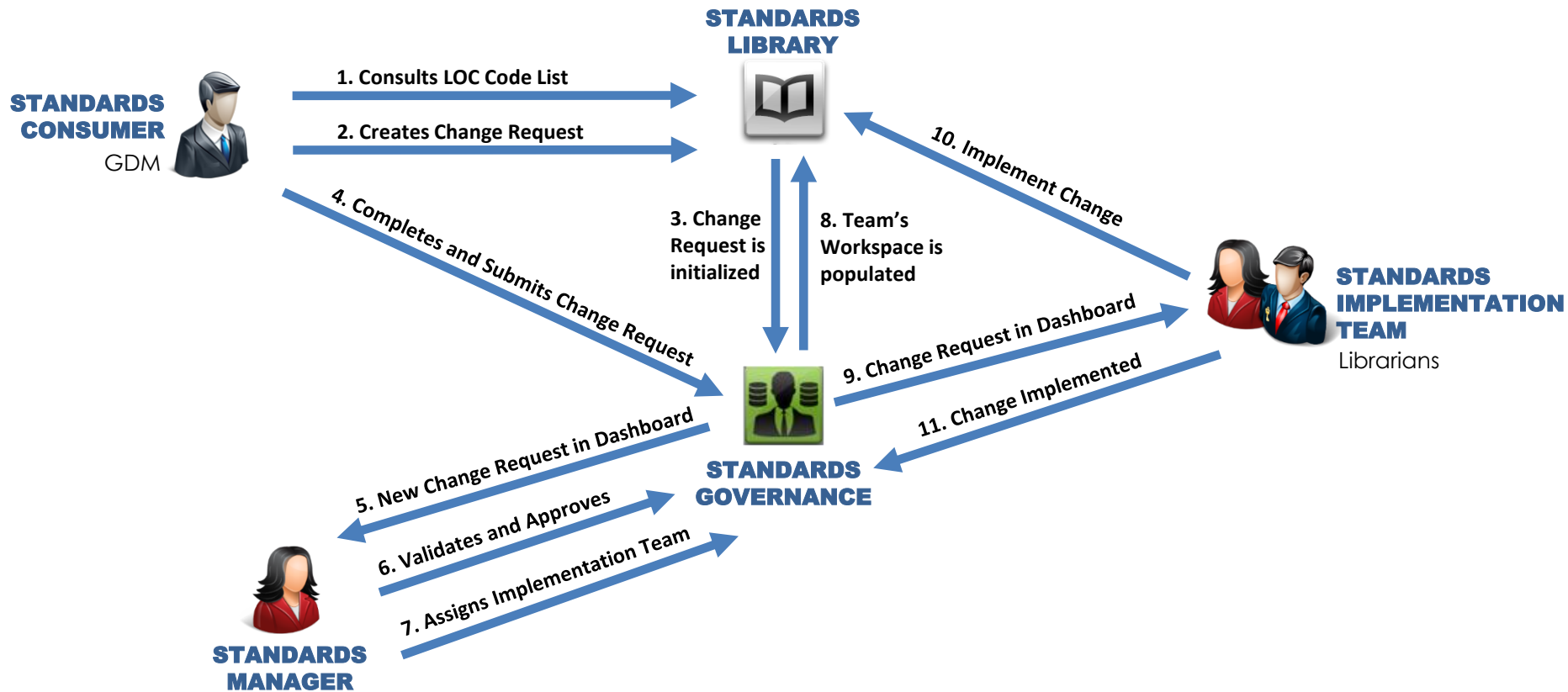
- **Multiple Standards Governance implementation strategies**
 - Governance as an **ad-hoc process** that MDR users must follow
 - Governance as a **standard process**, supported by a tool, that MDR users must follow
 - Governance as an MDR **integrated process**

- **BDLS implemented a Standards Governance Module integrated with an MDR**

Demo Scenario

- **MDR contains organizational controlled terminology standard based on SDTM CT release of March 2015**
- **GDM is setting up a study for which the use of a new LOC code released in June 2015 would be helpful**
- **Demo video will show how this organizational standards change is requested, approved, implemented and made available, all in the MDR**

Demo Scenario



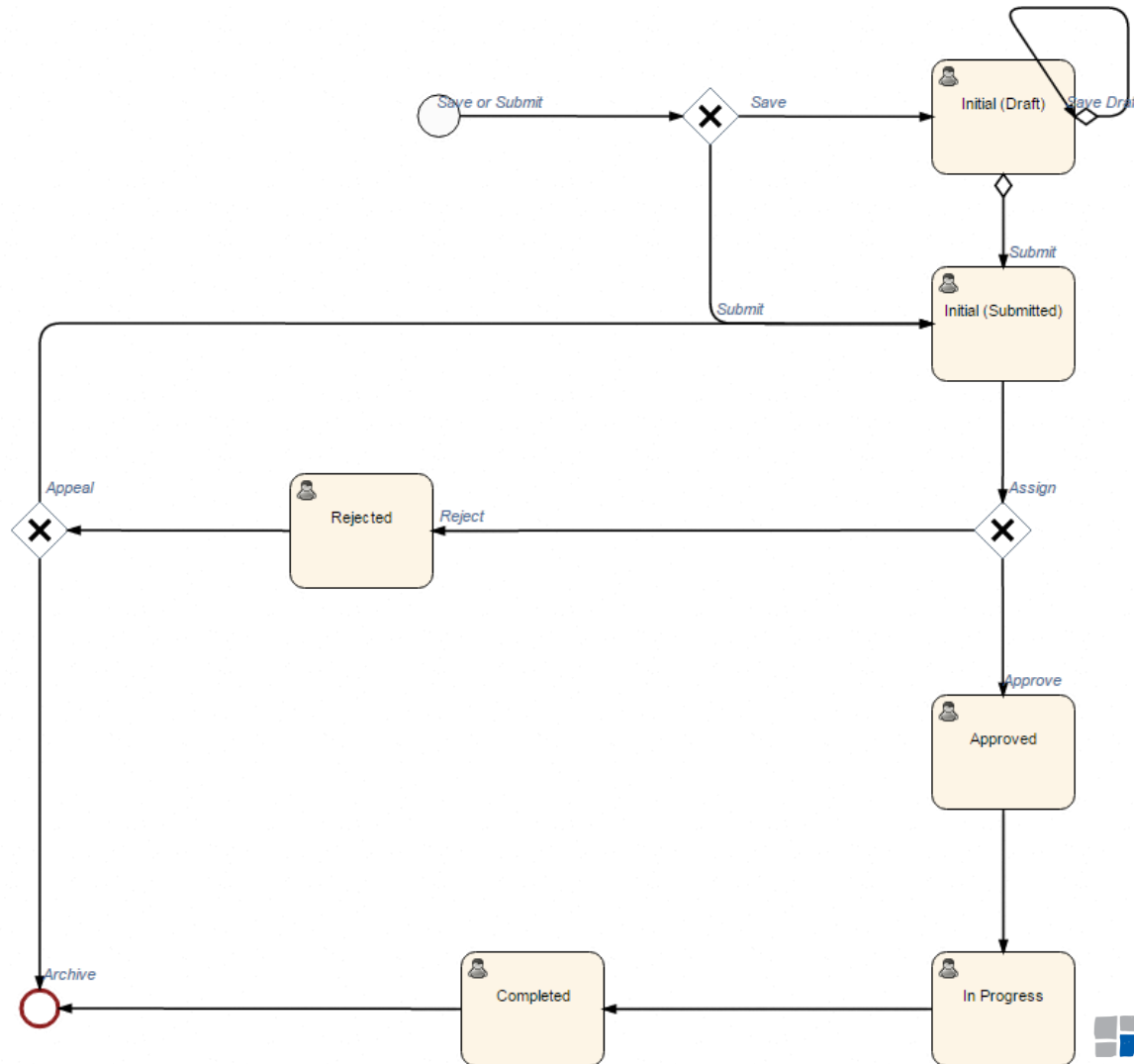


**DEMO
TIME!**

Configurable Governance Processes

- **This general process and actors are not one-size-fits-all**
 - MDR and governance tool should **adapt to organization**, not the other way around
- **BDLS's implementation of Standards Governance integrates with external workflow engine**
 - Customized **roles**
 - Different **processes** for different types of operations (e.g. creation of new standard and change of existing standard)
 - Different **states** for the change request within a process
 - Different **fields**, mandatory fields and options per state

Configurable Governance Processes



Conclusion

- Governance becomes necessary due to increasing quantity and relevance of Data Standards
- Governance should promote continuous improvement of Data Standards, considering input both from end users and experts
- Integration between MDR and tools supporting Governance has a number of benefits (seamless experience, traceability of changes, ...)
- Tools supporting governance should be configurable, so that it adapts to the organization and not the other way around



Thank you