

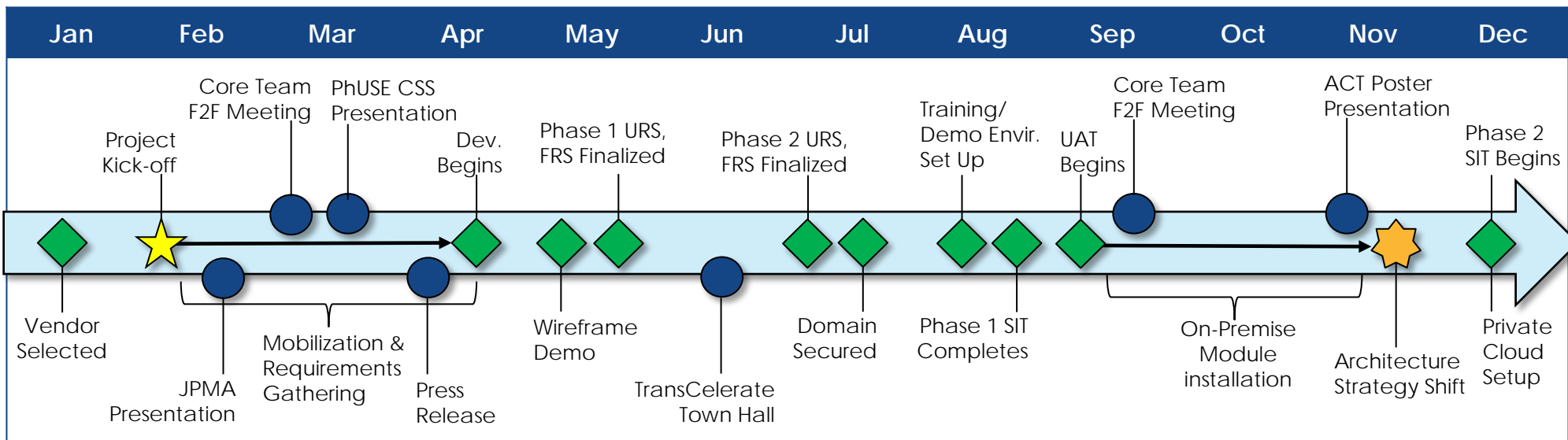


# Toxicology Data Sharing Initiative *Update*

March 2018

# 2017 Initiative Milestones

## Toxicology & Background Control Data Sharing



### Key Milestones

- Technology partner selected
- Project kick-off
- User Requirements, Functional Requirements, System Design Specifications completed
- System & integration testing commenced
- Architecture strategy shift: decision to move to a fully cloud-based solution
- External engagement: JPMA, PhUSE, ACT, kick-off press release



# DataCelerate System Capabilities

## Toxicology & Background Control data modules

Core Capability	Use Case Focus
<b>Identity Management</b>	<ul style="list-style-type: none"><li>▪ Semi-automated de-identification of PII (personally identifiable information) and redaction of commercially sensitive information for structured and unstructured data</li></ul>
<b>Import &amp; Export</b>	<ul style="list-style-type: none"><li>▪ Import of structured (e.g. CDISC) and unstructured data (e.g. PDF)</li><li>▪ Unit conversion for lab values</li><li>▪ Export of full studies and filtered search results</li></ul>
<b>Data &amp; Document Management</b>	<ul style="list-style-type: none"><li>▪ Separate background control &amp; toxicology databases</li><li>▪ Linkages between associated toxicology data sets</li></ul>
<b>Search</b>	<ul style="list-style-type: none"><li>▪ Enhanced search &amp; filtering capabilities across unstructured &amp; structured data</li></ul>
<b>Data Visualization</b>	<ul style="list-style-type: none"><li>▪ Visualization tools for structured datasets</li></ul>



# Workflow & Architecture

## Toxicology & Background Control data modules

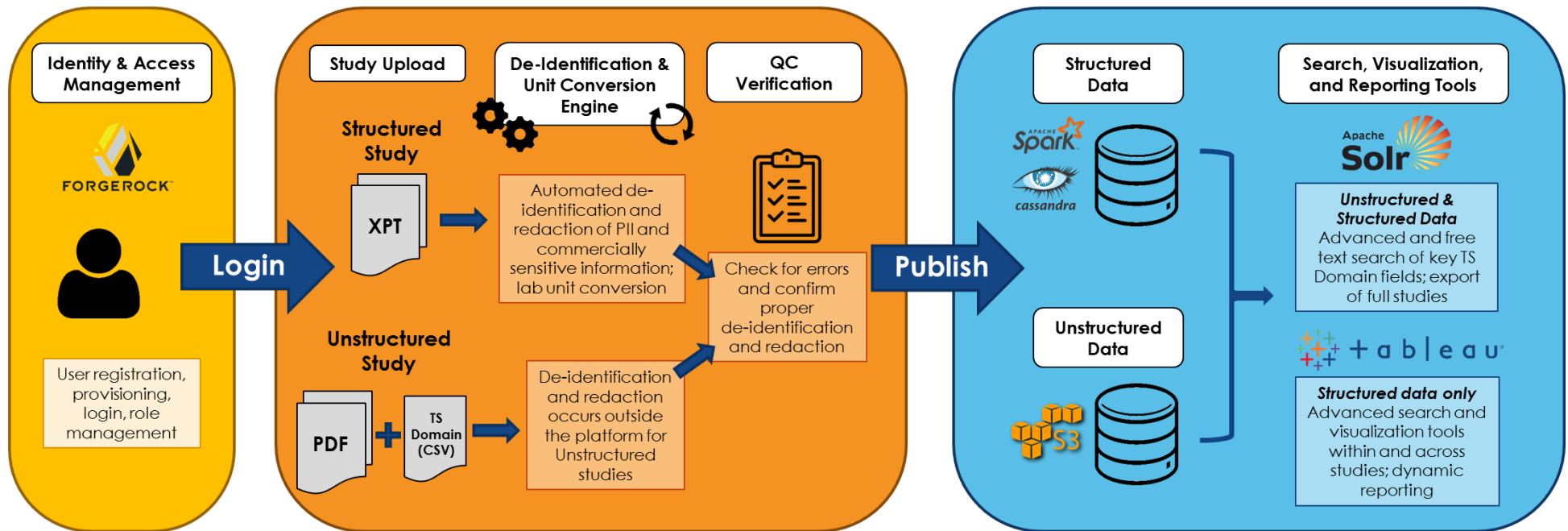


### Private Cloud

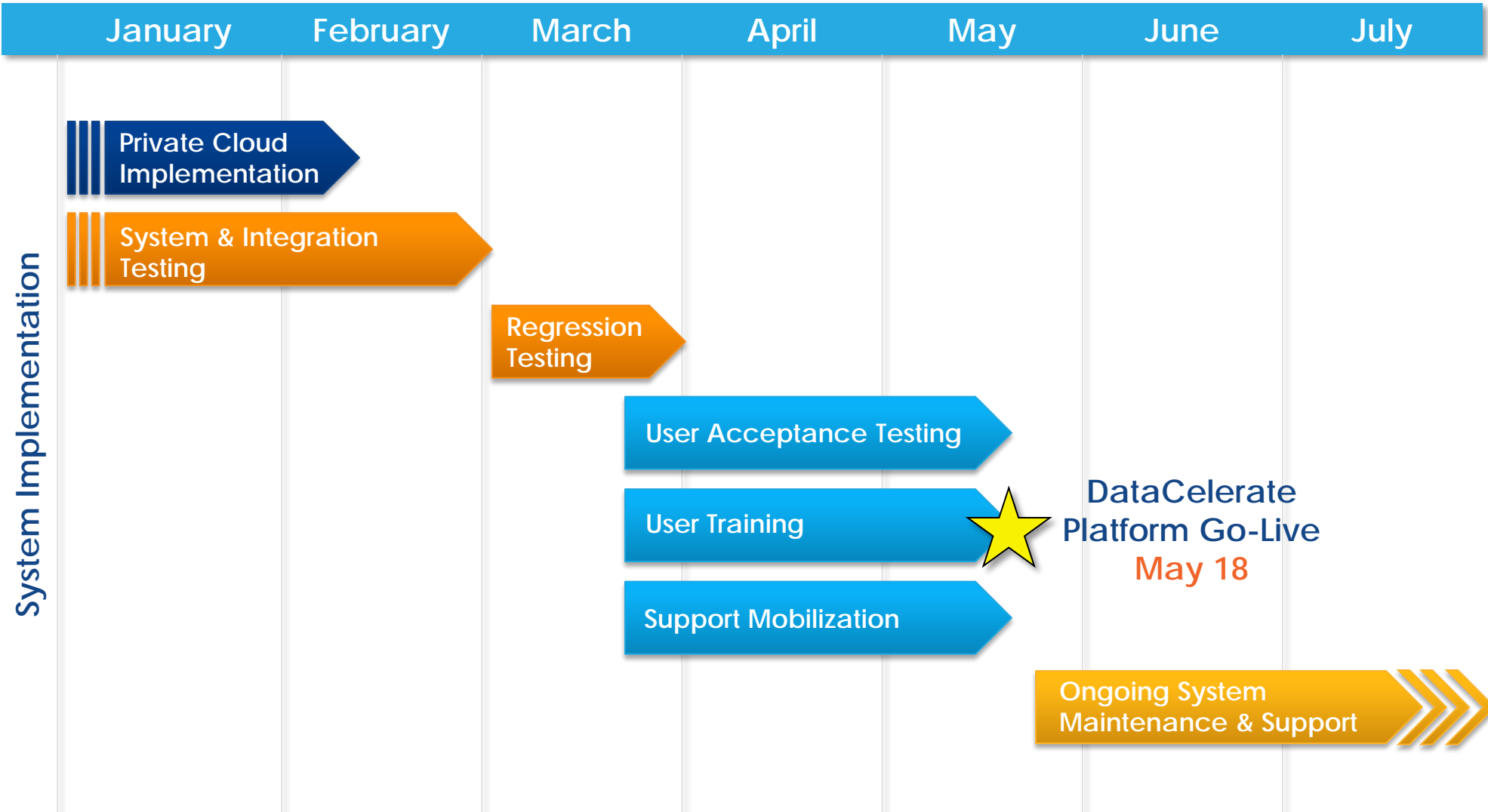
Separate, secure Member Company partitions

### Shared Cloud

Accessible by all Member Companies



# 2018 Go-Live Schedule



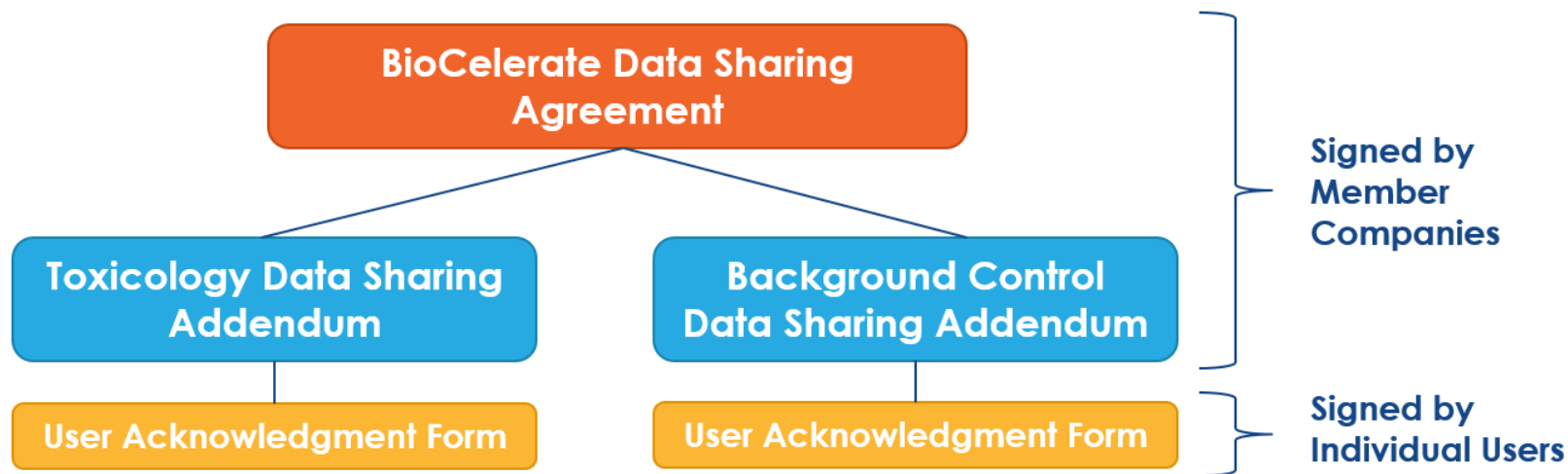
System Implementation

**DataCelerate  
Platform Go-Live**  
May 18

Ongoing System  
Maintenance & Support

# BioCelerate Data Sharing Agreements

Data sharing amongst BioCelerate participants is governed by formal data sharing agreements, required for participation



## Key Elements Addressed in DSAs

- Data content & contribution requirements
- Removal of personally identifiable information (PII) & sensitive commercial information
- Withdrawal of data
- Grounds for termination
- Ownership of data / permissible use of data



# DataCelerate: 3-year Roadmap

