

Managing a custom-built SCE: The J&J journey for SPACE

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Skin cells at 20x magnification

About the Presenters

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Acknowledgements

Business Owners	Olivier Leconte, Bev Hayes, Sumesh Kalappurakal
Business Leads	Mark Bynens, Marco Bertolino
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Support Management	Peter Wang, Bart Leplae
QA	Roland Gasparini, Laurent Denu, David Ehrenfeld
Code Review Manager	Helena Brekalo
Technical Architect	Satish Murthy
R Subject Matter Expert	Nicholas Masel
Python Subject Matter Expert	Nicolas Dupuis

Agenda

- **Why Build Own SCE (again!) ?**
- **SPACE at a glance**
- **SPACE Implementation Methodology**
- **SPACE and open-source**
- **Future Landscape**

Why build own SCE (again)?

Expectations

Legacy system concepts fully endorsed by J&J Programming community

New SCE implementation must be cost-effective vs. ROI focus

Ability to incorporate new requirements in a timely basis

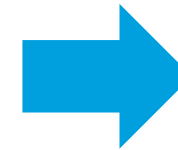
Requirements

Cloud solution with all required statistical packages including open-source

Study Code validation workflow should remain similar

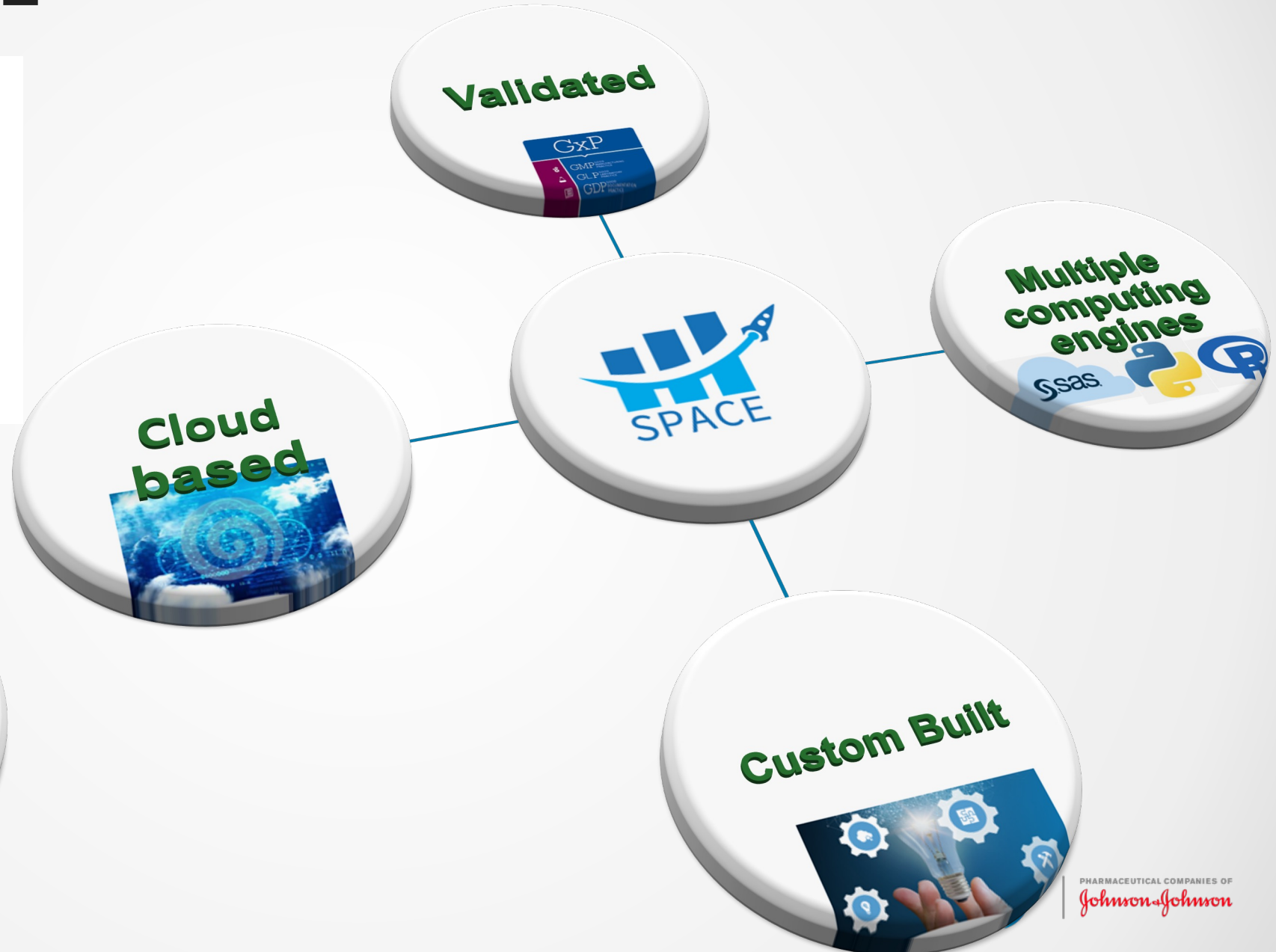
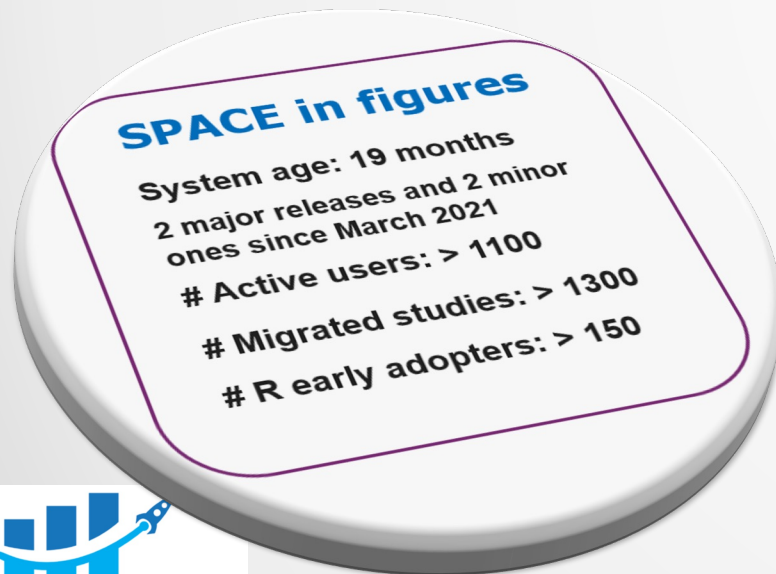
Ability to integrate with other J&J systems

Fully GxP compliant platform



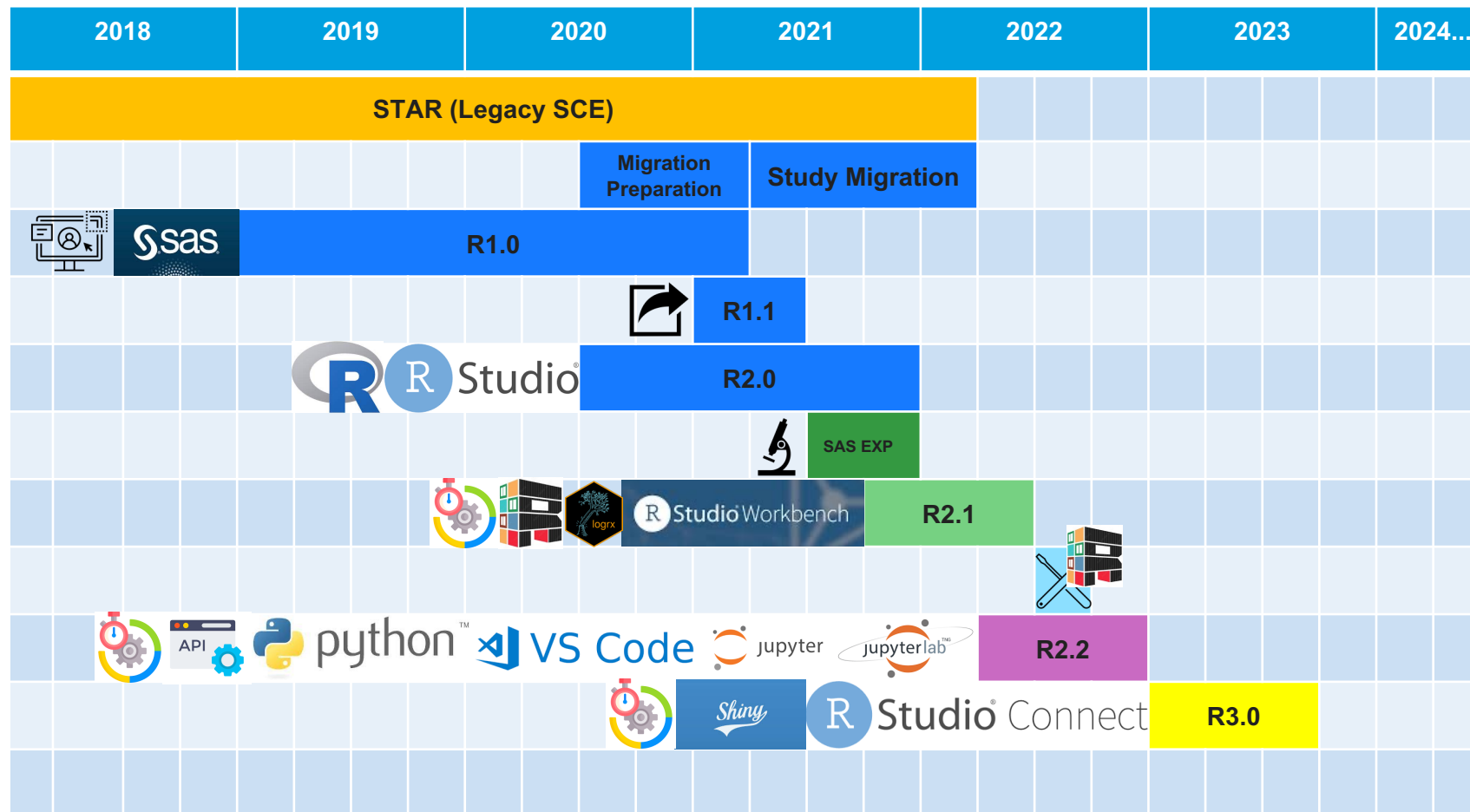
J&J accountable and responsible to implement roadmap

What is SPACE



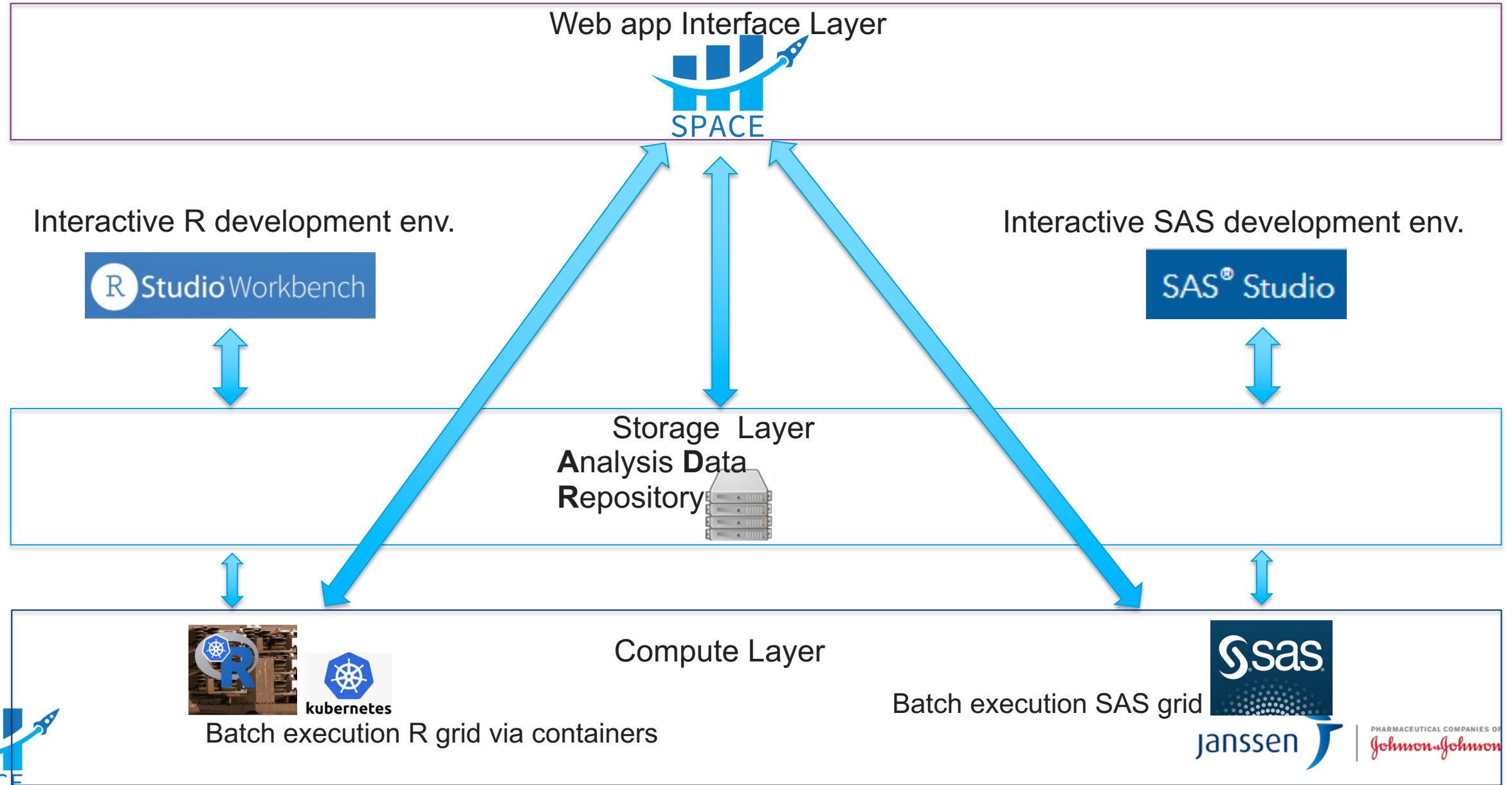
SPACE at a Glance (1)

Roadmap – *focusing on statistical capabilities*



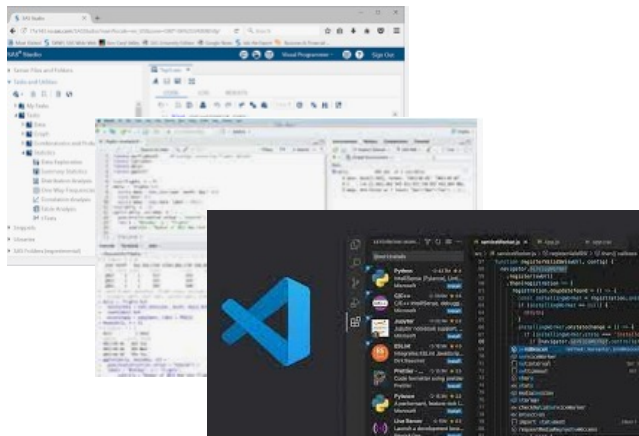
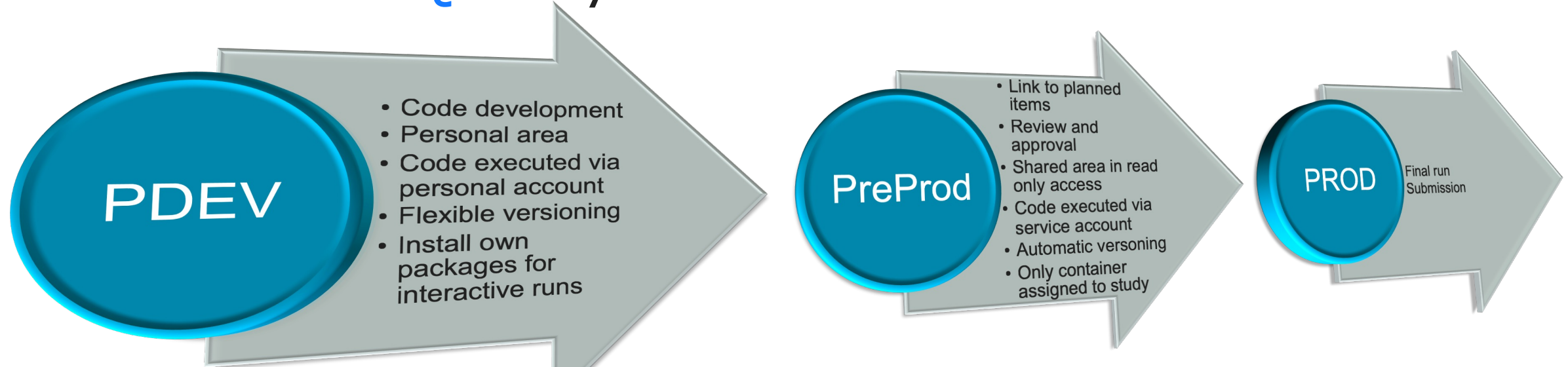
SPACE at a Glance (2)

Components



SPACE at a Glance (3)

Risk-Based Quality Review Workflow



The image shows two screenshots of the SPACE interface. The top screenshot displays the 'test_compound' component with a table of planned items. The bottom screenshot displays the 'p1.sas' component with a table of planned items.

Planned items	Title	Type	Level	Code	Programmer	Reviewer	Output Created	Status	Comments
☐	test_compound	test	TLF	Medium				Not ready	
☐	test.tlf	test	TLF	Low	mbert104	mbert104		Not ready	
☐	test.tlf	test	TLF	Low	test_compound	mbert104	2022-08-27 10:41	Not ready	

Planned items	Title	Type	Level	Code	Programmer	Reviewer	Output Created	Status	Comments
☐	p1.sas	test	TLF	Low	test_compound	mbert104	2022-08-27 10:41	Not ready	

Assign level, programmer & reviewer

Type
TLF

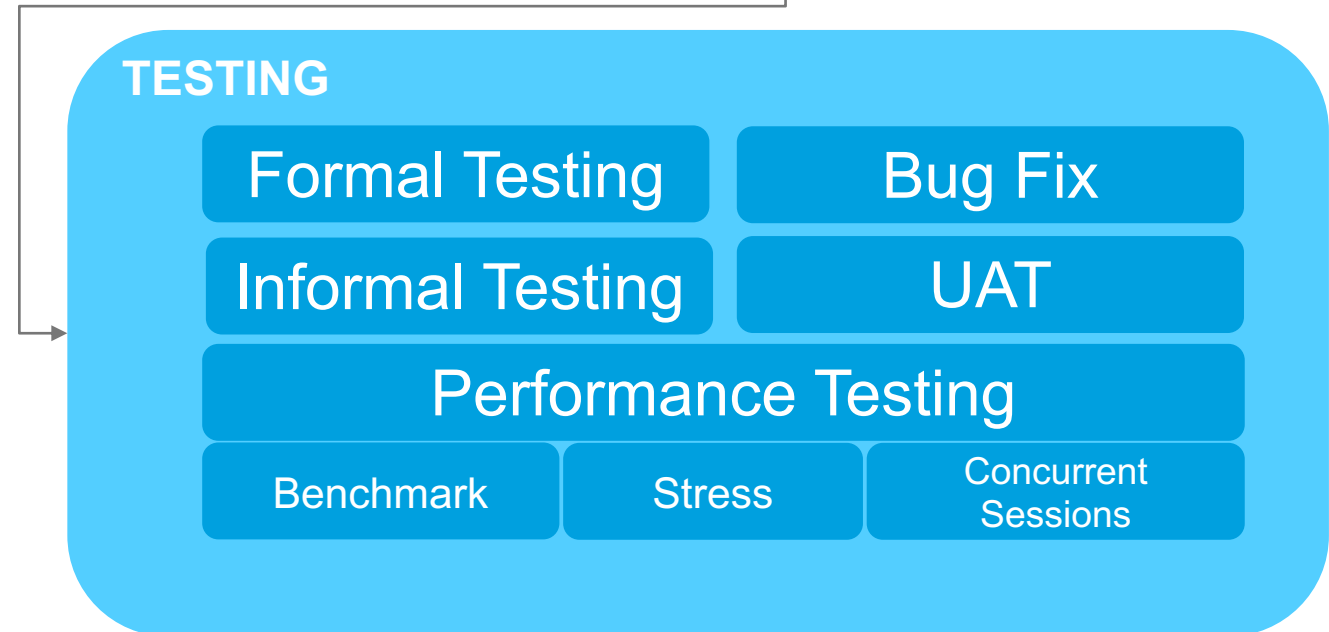
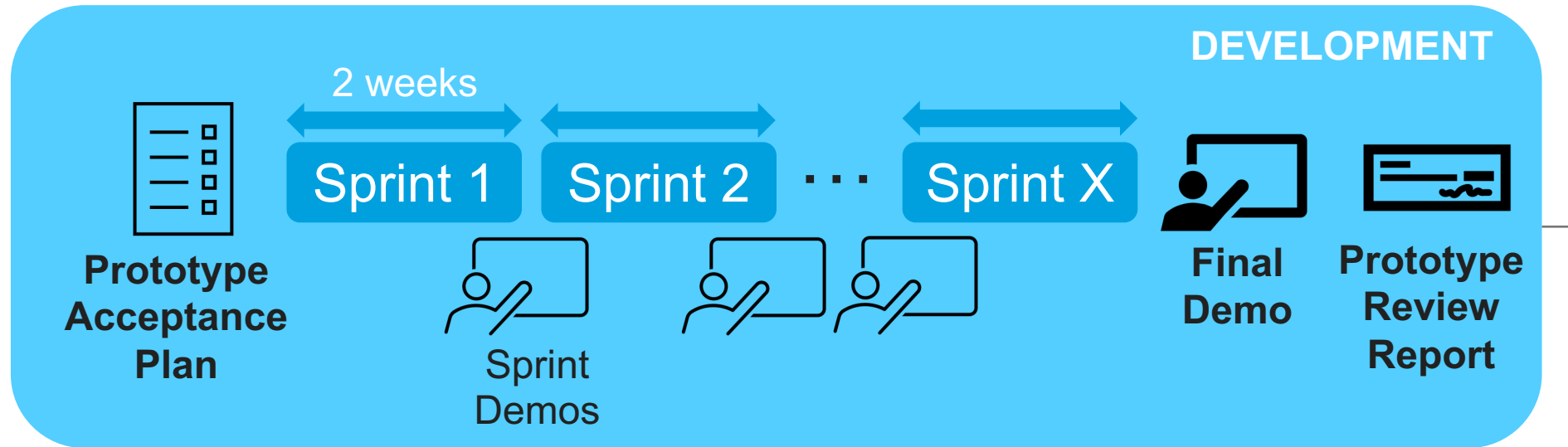
Level
Medium

Programmer

Reviewer

SPACE Implementation Methodology (1)

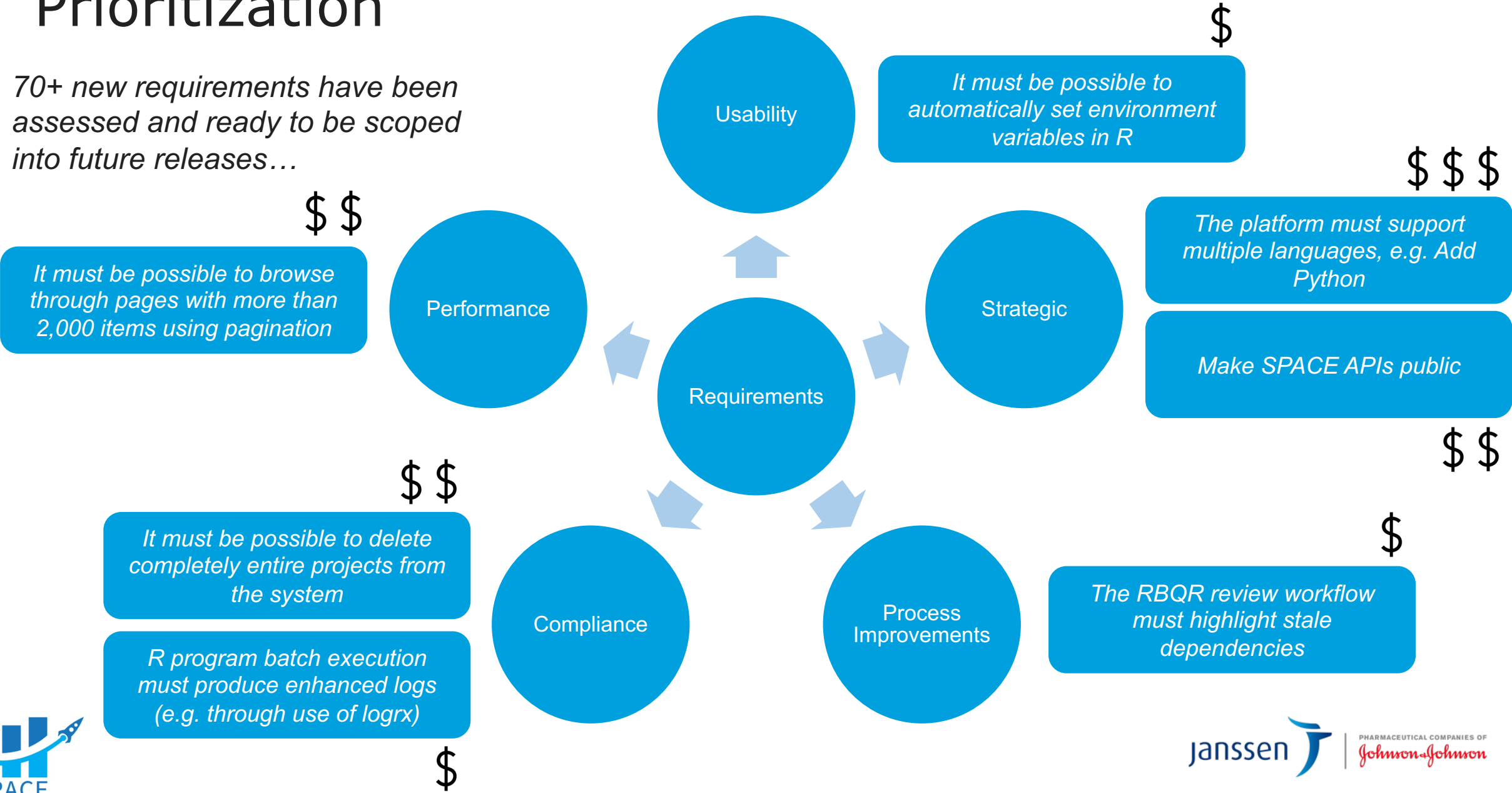
SDLC



SPACE Implementation Methodology (2)

Prioritization

70+ new requirements have been assessed and ready to be scoped into future releases...



SPACE and Open-Source (1)

Approach

- Partner with Vendor
- J&J to review requirements and test cases
- Vendor to deliver automated test scripts
- J&J can run test scripts and **deploy** validated packages in containers in a compliant manner

Compliance

Validation of Selected Packages

Ability to reuse and run different package versions

Same validation workflow than for SAS programs

Same handling of dependencies

Efficiency

Users can **install** new packages in their development areas

Open-source statistical components performance tested for expected number of users

Best in class web-based program editors

Collaboration

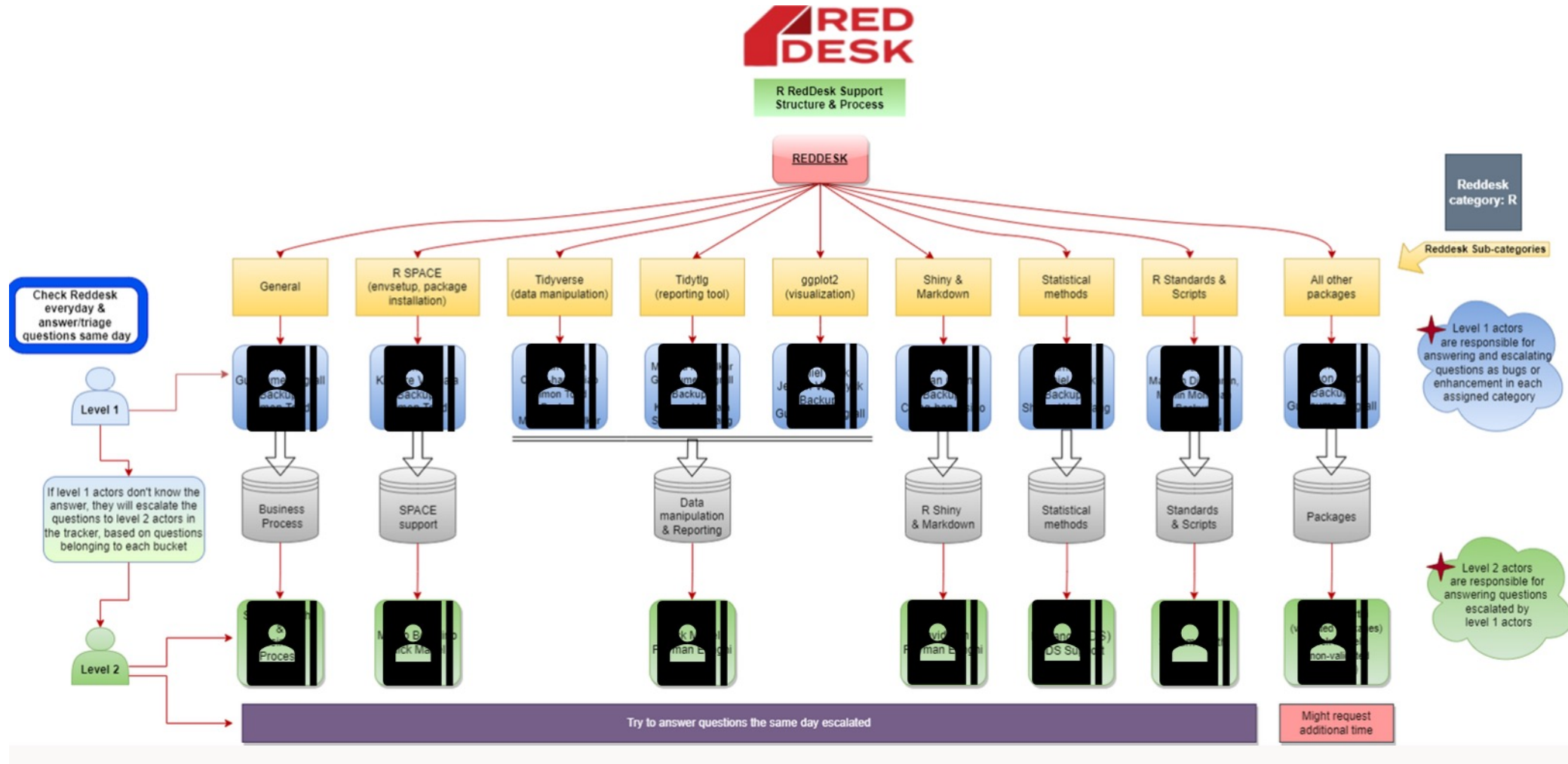


Rx Pharma

R
consortium

SPACE and Open-Source (2)

R Support Organization



Future Landscape

- RConnect - support R shiny directly in SPACE
- Integrate further Ad-hoc tools into SPACE
 - ADaM tools, output planning tools, bots-based tools...
- Expand usage of SPACE to other departments
 - Epidemiology, Biomarkers, Data Science, Safety, etc.

Questions?

Skin cells at 20x magnification