



From roadmap to reality

Advancing the data ecosystem in clinical research



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SDS Clinical

for more and faster insights

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Data sharing

Make data findable and accessible for a broad user spectrum

Compliance

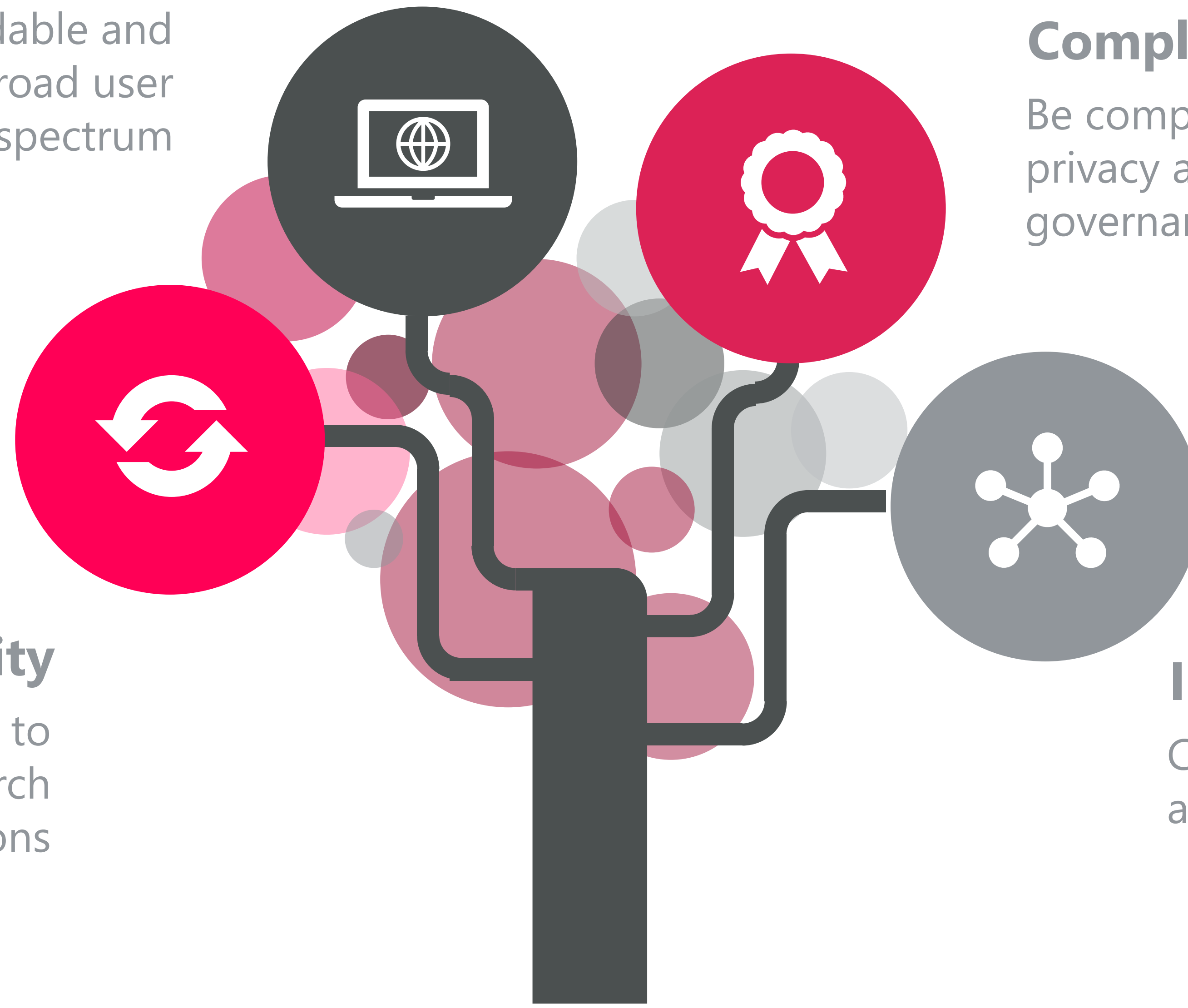
Be compliant on data privacy and data governance policies

Reusability

Harmonise data to answer new research questions

Interoperability

Connect between systems and divisions





THE ROADMAP

Phase 1

Establish state-of-the-art Clinical Data Environment

Phase 2

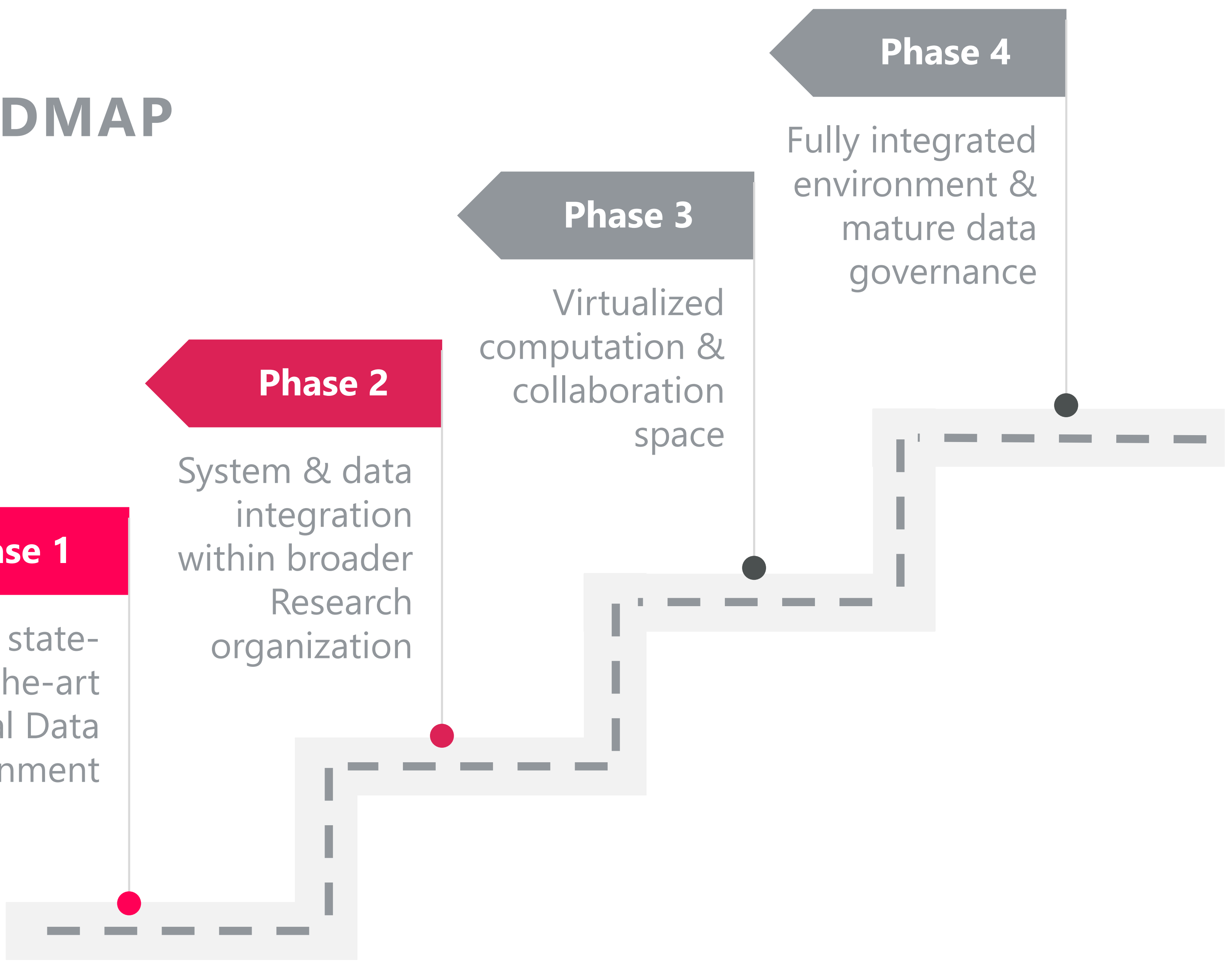
System & data integration within broader Research organization

Phase 3

Virtualized computation & collaboration space

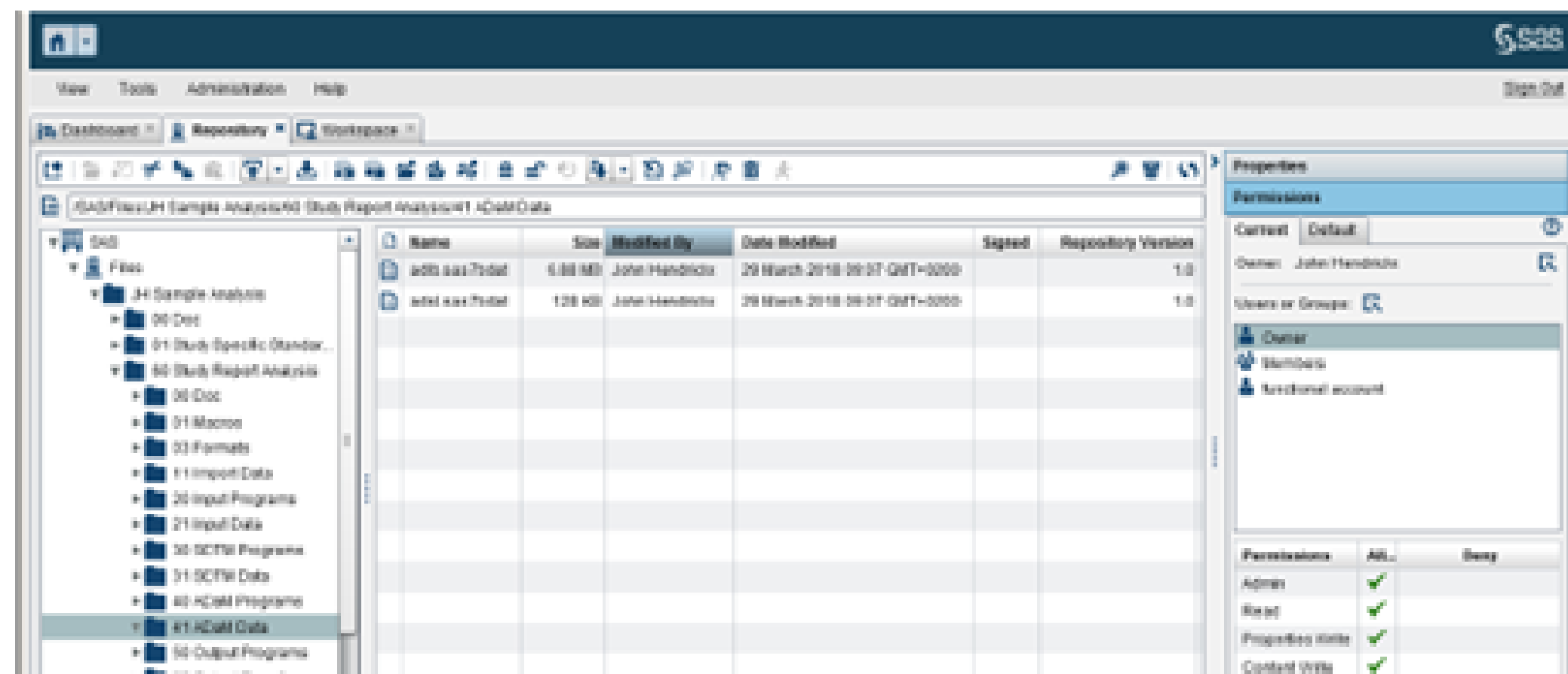
Phase 4

Fully integrated environment & mature data governance



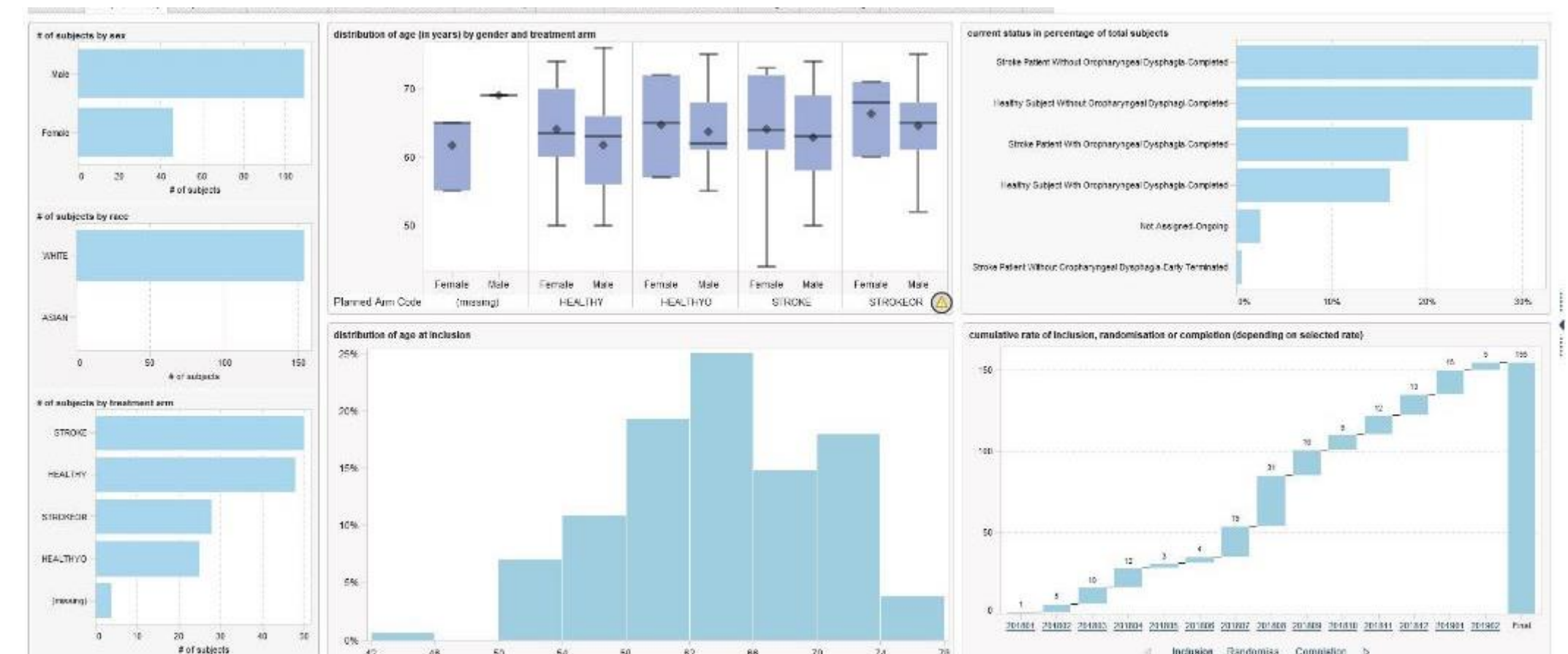
SDS Clinical

implement shared and auditable way of working



Life Sciences Analytical Framework

Transform, analyse and report on clinical trial data
Robust Access control and full audit trail
Efficient workflow management



Virtualization and Visualization

Making data **findable** and accessible
Provide **dashboards** and reports
Stay **compliant** and respecting privacy regulation

Investigating studies with Asian infants with a specific ingredient 6

until now...

**Does anybody
know studies
with this
ingredient?**

**... but what
about the study
design and the
population?**

**Yes! I think
you should
investigate
these studies.**

**Found some
studies! But do
they contain the
same ingredient
level?**



Study Catalog

Entry point for studies and data



Search for studies
Search studies for specific terms

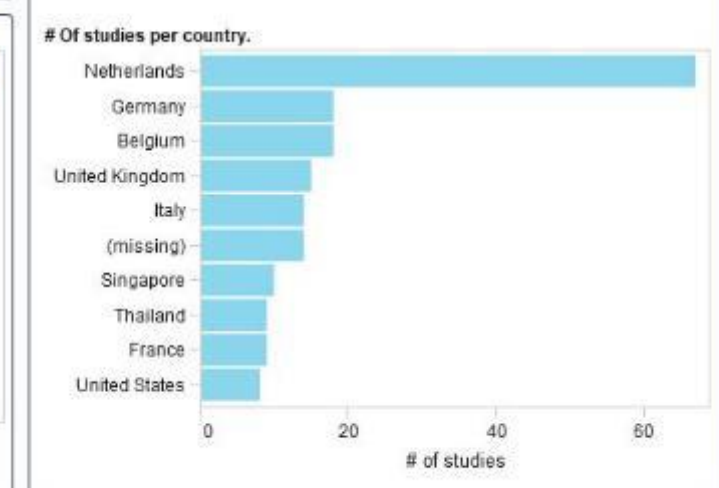
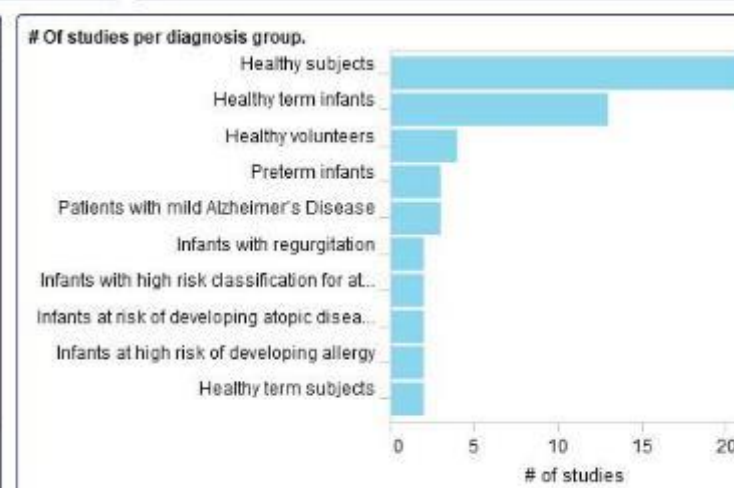
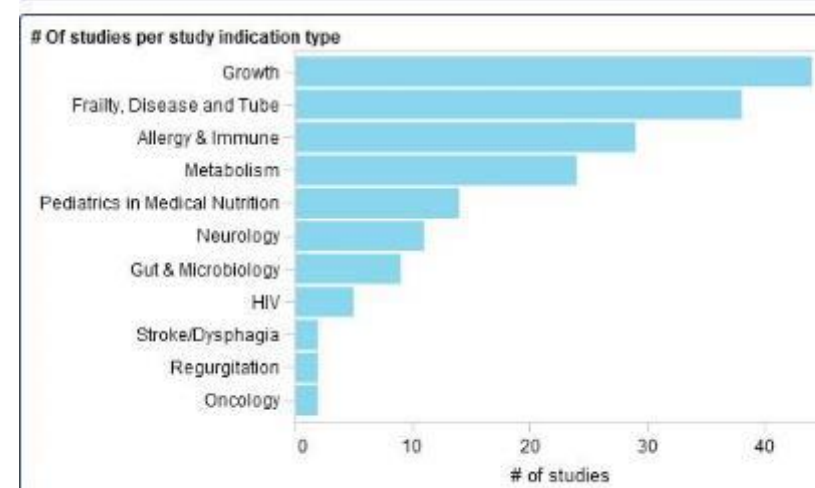
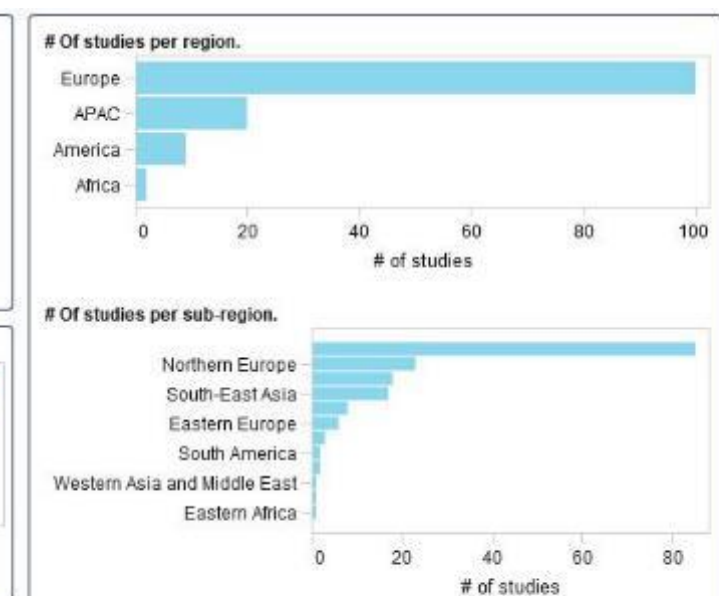
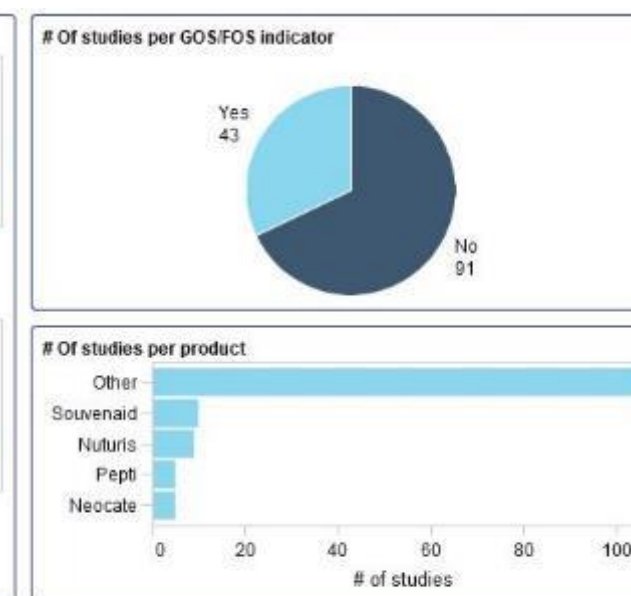
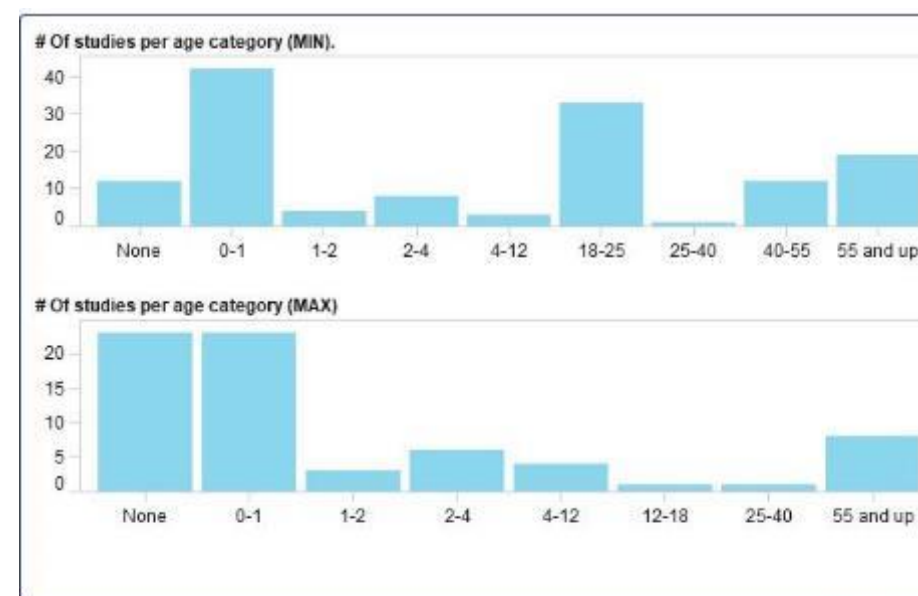


Analyse and compare
Analyse and compare metadata
with visualizations



Extract data
Download data for further use –
while staying compliant

Study Catalog									
Study Characteristics									
Study Details									
# of studies 134	Search for... a value	Specific search: Search:	Select a region: Africa Ameri... APAC Europe	Select a division: AMN ELN	Randomized? Yes No N/A	01Jan2003 01Aug2018			
Study Name	Study ID	Planned Study Start Date	Study Title	Clinical Study Sponsor Original	Planned Number of Subjects	Study Primary Objective	Study Secondary Objective	Primary Outcome Measure	
AAA	NTS.1.P/H	2015-09-03	Amino Acid bioAvailability of different proteins	Nutricia Research B.V.	13	To investigate whether the protein mix is related to a faster postprandial amino acid bioavailability compared to casein as measured by the t½ of the iAUC.	Whether the amino acid profile of pea, soy and whey protein and the protein mix are different from each other and different from casein.; The effect of adding calories (fat, carbohydrates) and micronutrients on the amino acid profile by comparing the protein mix and the complete tube feed containing this protein mix; What is the impact of different non coagulating proteins and casein on gastric emptying, postprandial fullness and safety.	The time to reach half increme sum of all amino acids (total A	
ACROPOLIS	Tub.1.C/A/O	2008-10-06	Evaluation of gastrointestinal tolerance of a new enteral nutrition formula	Numico Research B.V.	60	To investigate the gastrointestinal tolerance of NewNutrison Multi Fiber in comparison with Nutrison Multi Fiber.		Tolerance is investigated by m gastrointestinal symptoms.; B stool frequency; Gastrointestr following GI symptoms: nause constipation; Incidence of gas volume of product administrati	
ACROPOLISII	Tub.7.C/A	2011-07-01	Gastrointestinal tolerance of a new enteral nutrition composition in hospitalised patients	Danone Research B.V.	100	To investigate the gastrointestinal tolerance of the new tube feed composition in comparison with the control tube feed composition	To investigate the volume of intake of the new tube feed composition in comparison with the control tube feed composition.	Gastrointestinal tolerance; De diarrhea, constipation); Gastro reflux, regurgitation, vomiting, pain; Number of days target ar (<90% of target volume) due to on the first day, and 1200 ml of requirements on other days)	
ARENA	Sip.1.C/B	2008	Amino acid bioavailability in healthy elderly after bolus intake of a high whey-protein, leucine-rich, low-caloric oral nutritional supplement	Danone Research B.V.	12	To investigate the effect of a high whey-protein, leucine-rich, low-caloric oral nutritional supplement (ONS) compared to a high casein-protein, low-caloric ONS on serum amino acid, insulin, and glucose levels, during 4 hours after bolus intake in healthy elderly subjects. (A vs. B)	To investigate the effect of a high whey-protein, leucine-rich, high-caloric ONS compared to a high casein-protein, high-caloric ONS on serum amino acid, insulin, and glucose levels, during 4 hours after bolus intake in healthy elderly subjects. (D vs. C); To investigate the effect of a low-caloric density compared to a high-caloric density of ONS on serum amino acid, insulin, and glucose levels, during 4 hours after bolus intake in healthy elderly subjects. (A, B vs. C, D); To investigate the interaction between protein source and caloric density of ONS on serum amino acid, insulin, and glucose levels, during 4 hours after bolus intake in healthy elderly subjects.	Maximum serum leucine conc	
ASIANNUTRITIONALSIA	Alz.1.C/O/O		An exploratory study to compare the differences in nutritional status between patients with mild and moderate Alzheimer's disease (AD) and cognitively intact healthy people in an Asian population	Nutricia Research Singapore	225	The objective of this study is to explore the differences in nutritional status between cognitively intact healthy people and subjects with mild and moderate AD.		1. Nutritional Status in blood s acid profile e.g. docosaexaend phosphatidylcholine DHA (PcD profile e.g. DHA / EPA / PcDHA types of phospholipids (e.g. P Ce, and others) and their spec Homocysteine, Vitamin B6, Fo Vitamin D	



Reset bar chart filters

Reset

Release

Select studies:

- ☐ AAA
- ☐ ACROPOLIS
- ☐ ACROPOLISII
- ☐ ANSS
- ☐ ARENA
- ☐ ASSIGN
- ☐ ATOS
- ☐ AUTISM
- ☐ AWARE

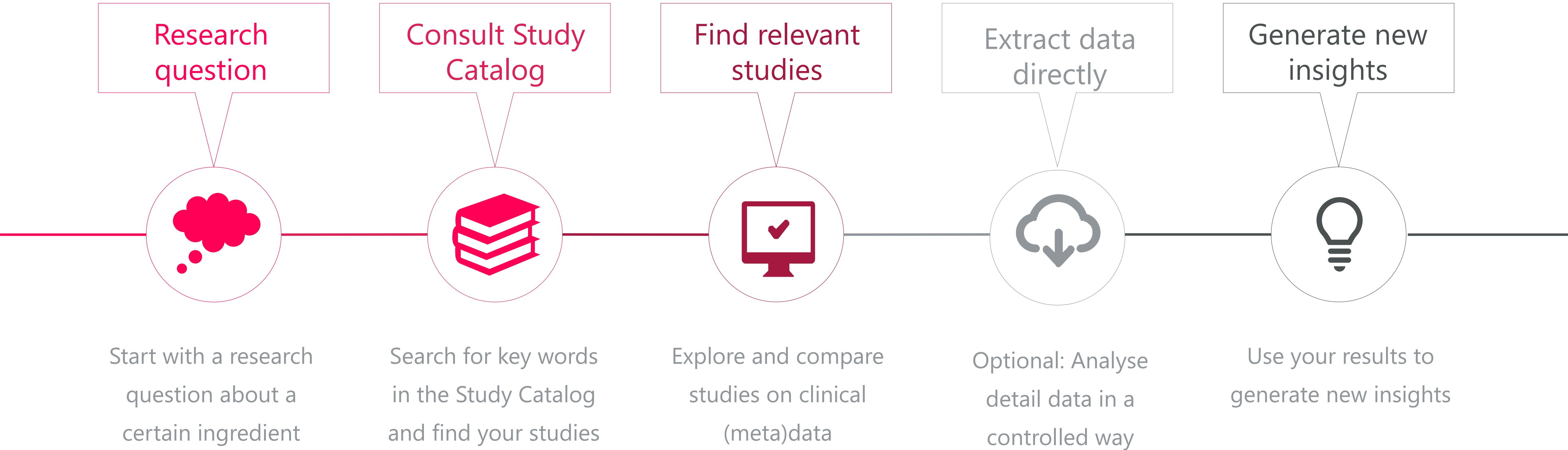
Compare selected studies



Investigating studies with Asian infants with a specific ingredient

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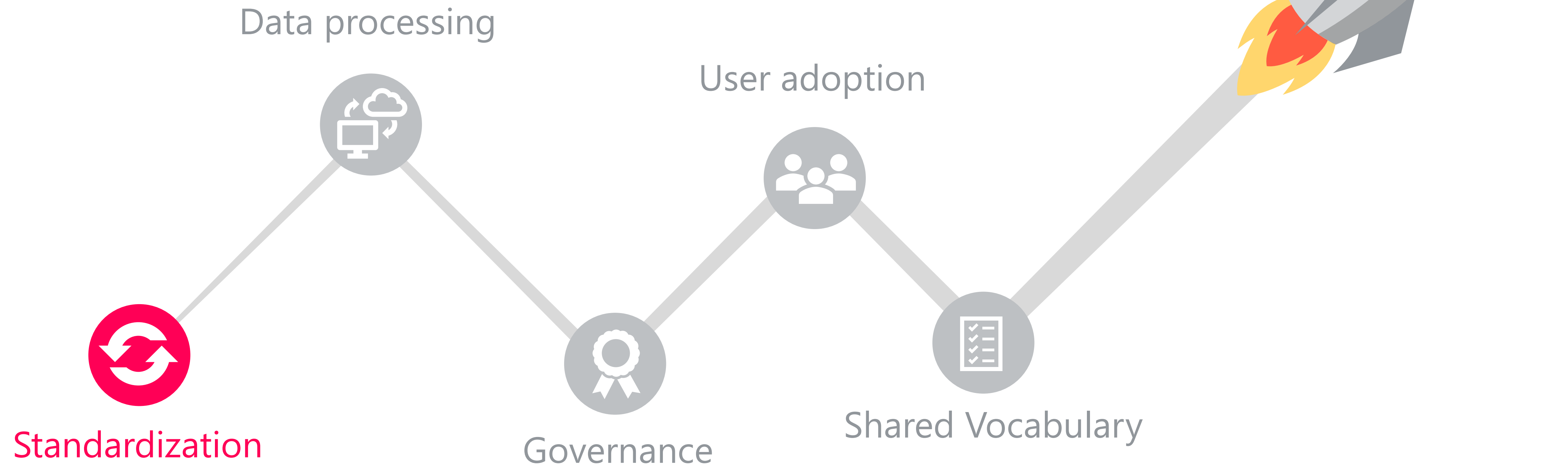
... with the Study Catalog



Launching the Study Catalog

extensive preparations

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Launching the Study Catalog

extensive preparations

10

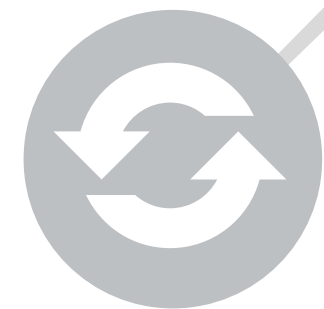
Data processing

User adoption

Standardization

Governance

Shared Vocabulary



The data processing layer

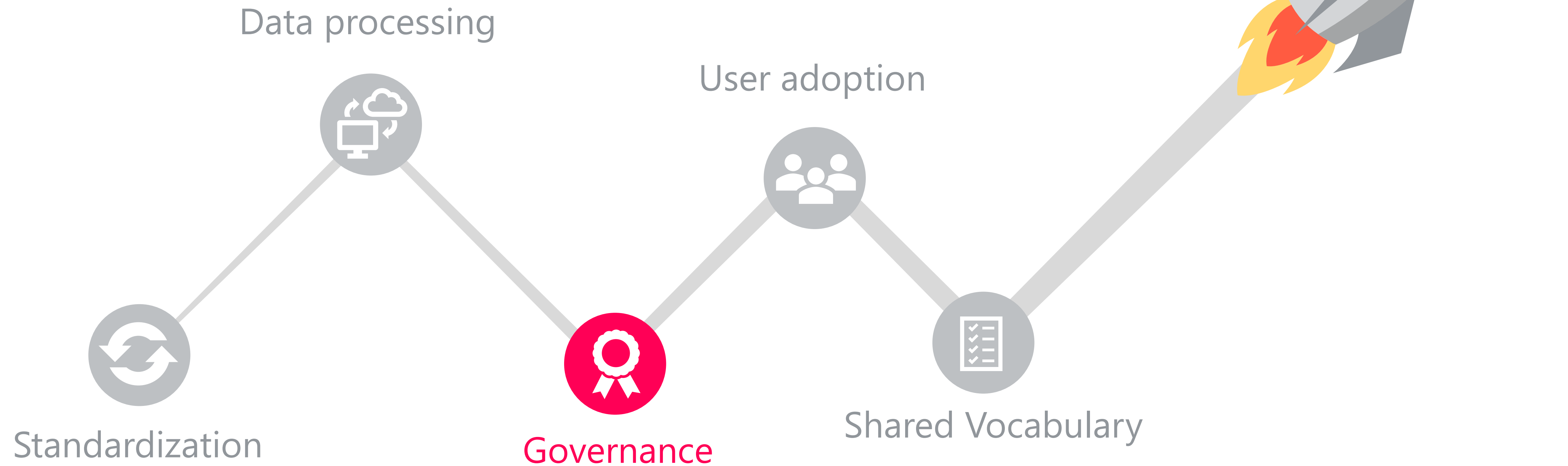
and more...



Launching the Study Catalog

extensive preparations

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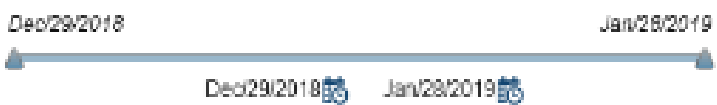


Governance

A scalable framework to monitor the environment



Top N reports displayed Top N tables displayed Report Last Accessed Actions overview Users Actions Administrative Detail LASR Server



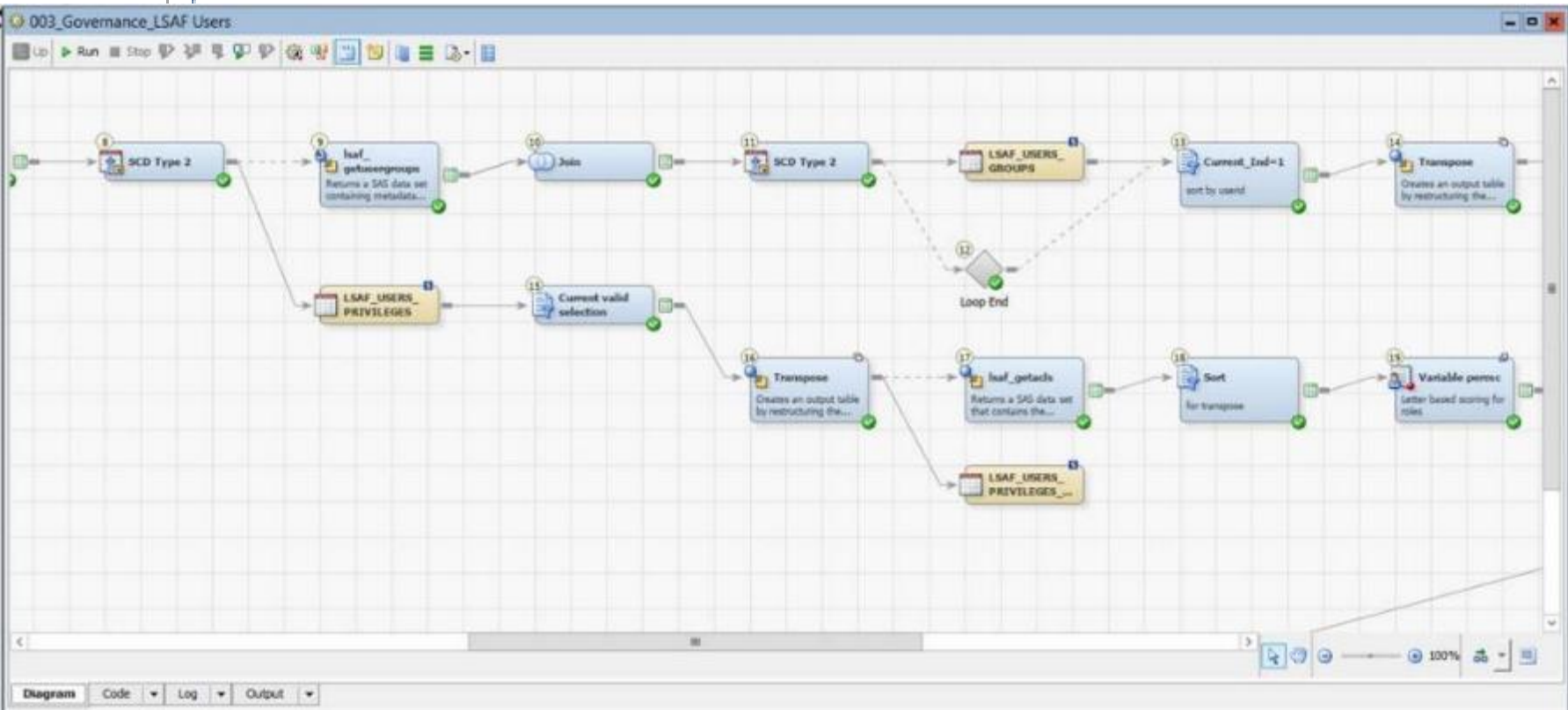
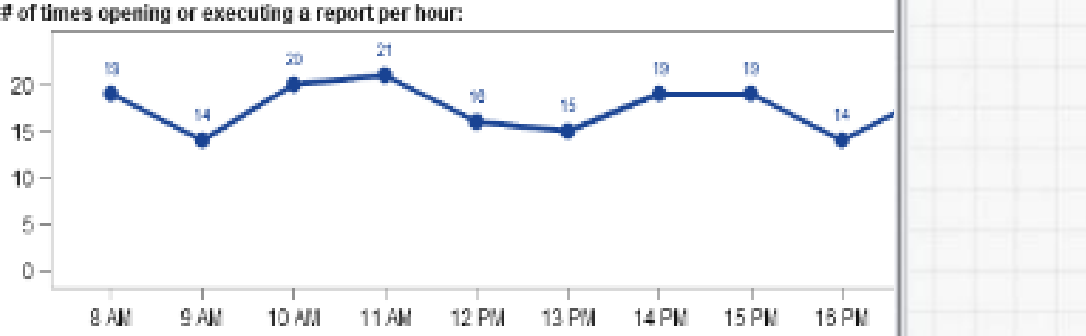
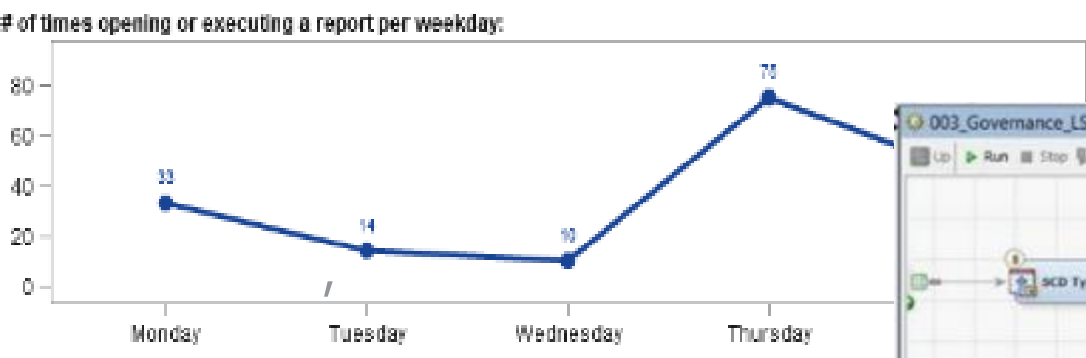
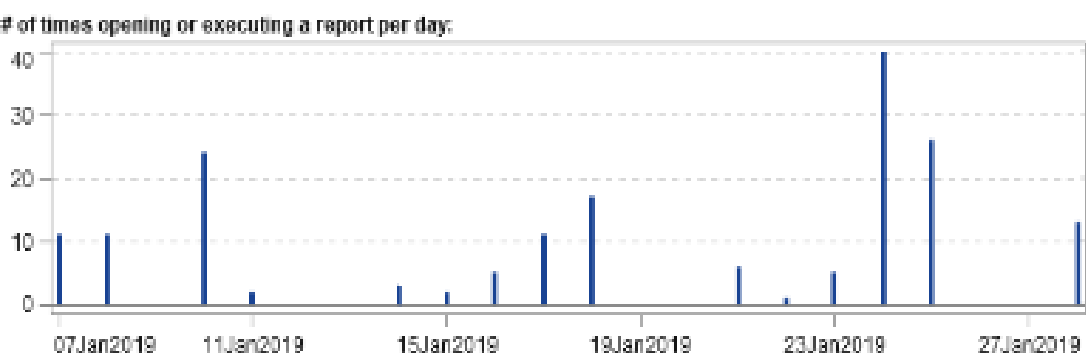
Select the Top N Reports to display 15

Select users:

- ☐ xad0axl
- ☐ xad0axw
- ☐ xad0axm
- ☐ xad0axn

Report	newlocation	Usage	Frequency Percent
Study Catalog (v0.9)(Report)	SBIP\METASERVER\ANALYTIC S_GENERIC\STUDY_CATALOG\CONCEPTS\Study Catalog (v0.9)(Report)	60	35.71%
Study Catalog - Design (v0.9)(Report)	SBIP\METASERVER\ANALYTIC S_GENERIC\STUDY_CATALOG\CONCEPTS\Study Catalog - Design (v0.9)(Report)	15	8.93%
Security Report (v0.9)(Report)	SBIP\METASERVER\ANALYTIC S\GOVERNANCE\SECURITY_R EPORTING\CONCEPTS\Secur ity Report (v0.9)(Report)	15	8.93%
Design_Metadata_Dashboard (v0.5)(Report)	SBIP\METASERVER\ANALYTIC S_GENERIC\DATA_QUALITY\CONCEPTS\Design_Metadata_D ashboard (v0.5)(Report)	13	7.74%
Governance Dashboard(Report)	SBIP\METASERVER\ANALYTIC S\GOVERNANCE\SQL_LOGRE PORTS\Governance Dashboard(Report)	11	6.55%
Administrator Dashboard (v0.9)(Report)	SBIP\METASERVER\ANALYTIC S\GOVERNANCE\VA_USAG\B/C	11	6.55%

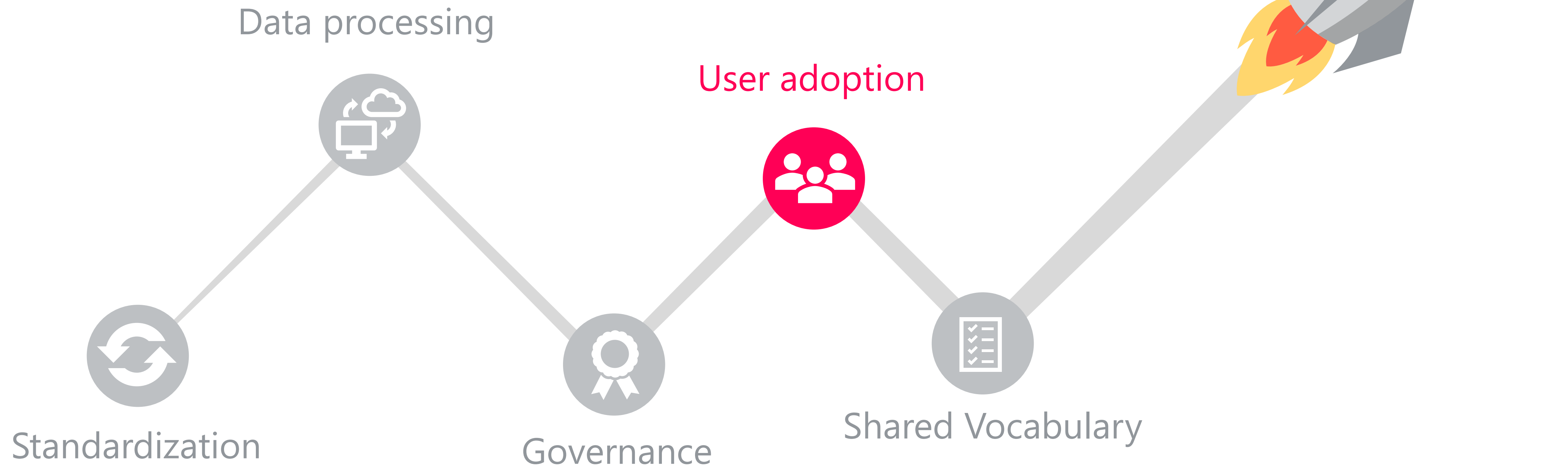
Activity per user



Launching the Study Catalog

extensive preparations

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User adoption

collaboration and involvement

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Information needs analysis

Develop inspiring and reliable prototypes

Find ambassadors, get them involved

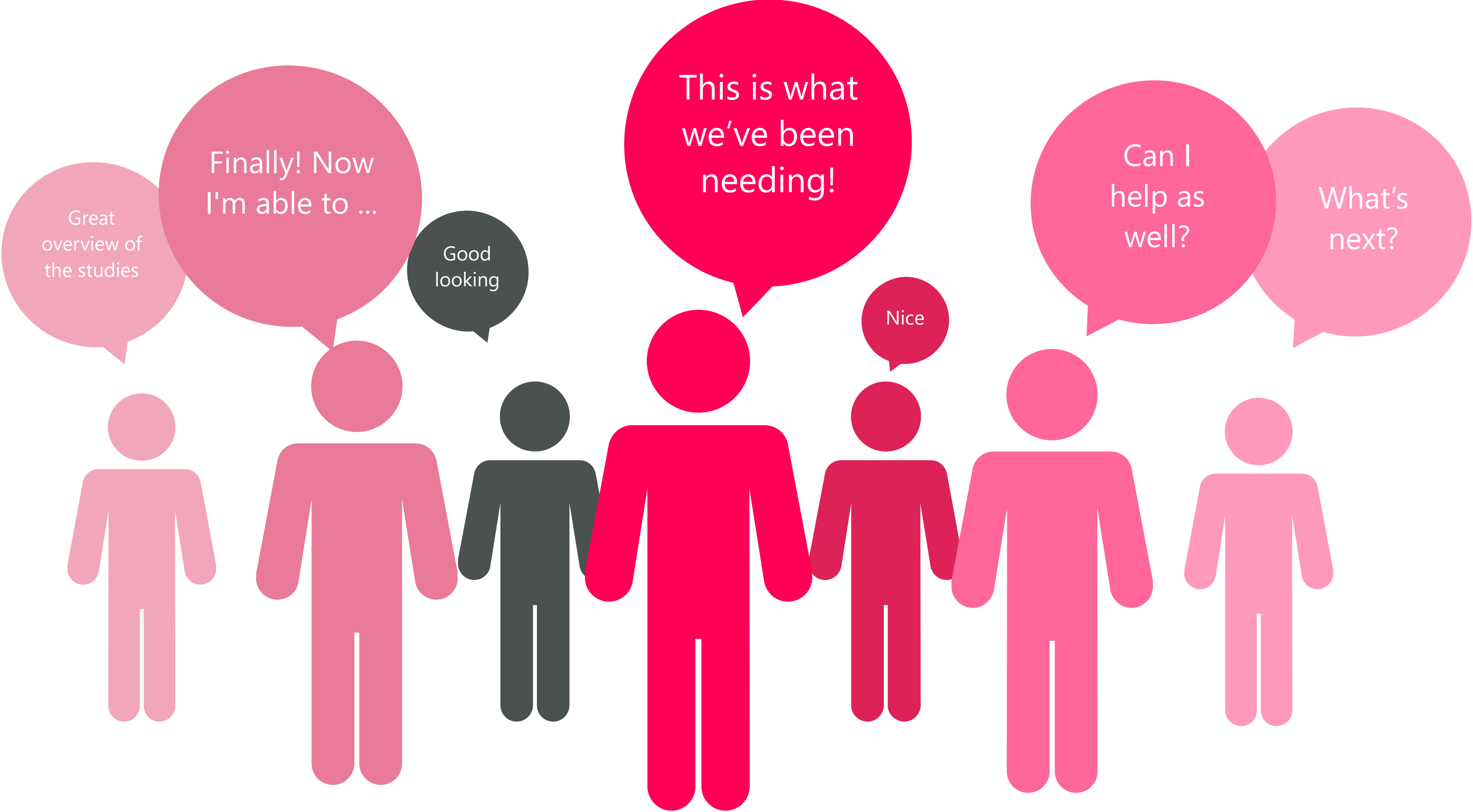
Develop together with end-users

Self-service and knowledge transfer



User adoption

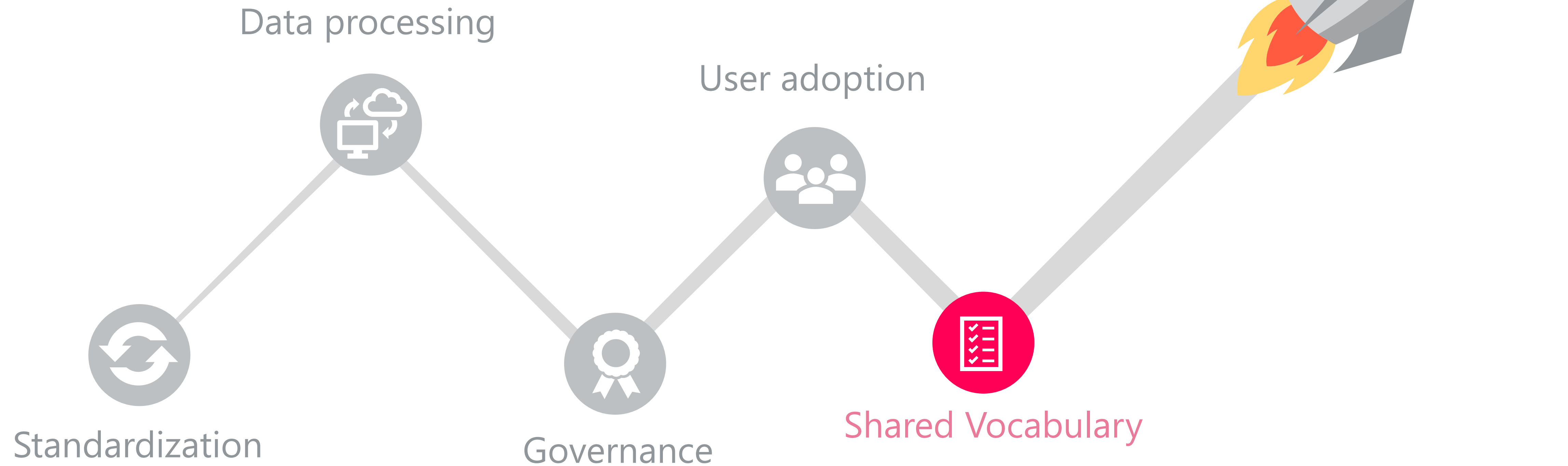
get everyone involved



Launching the Study Catalog

extensive preparations

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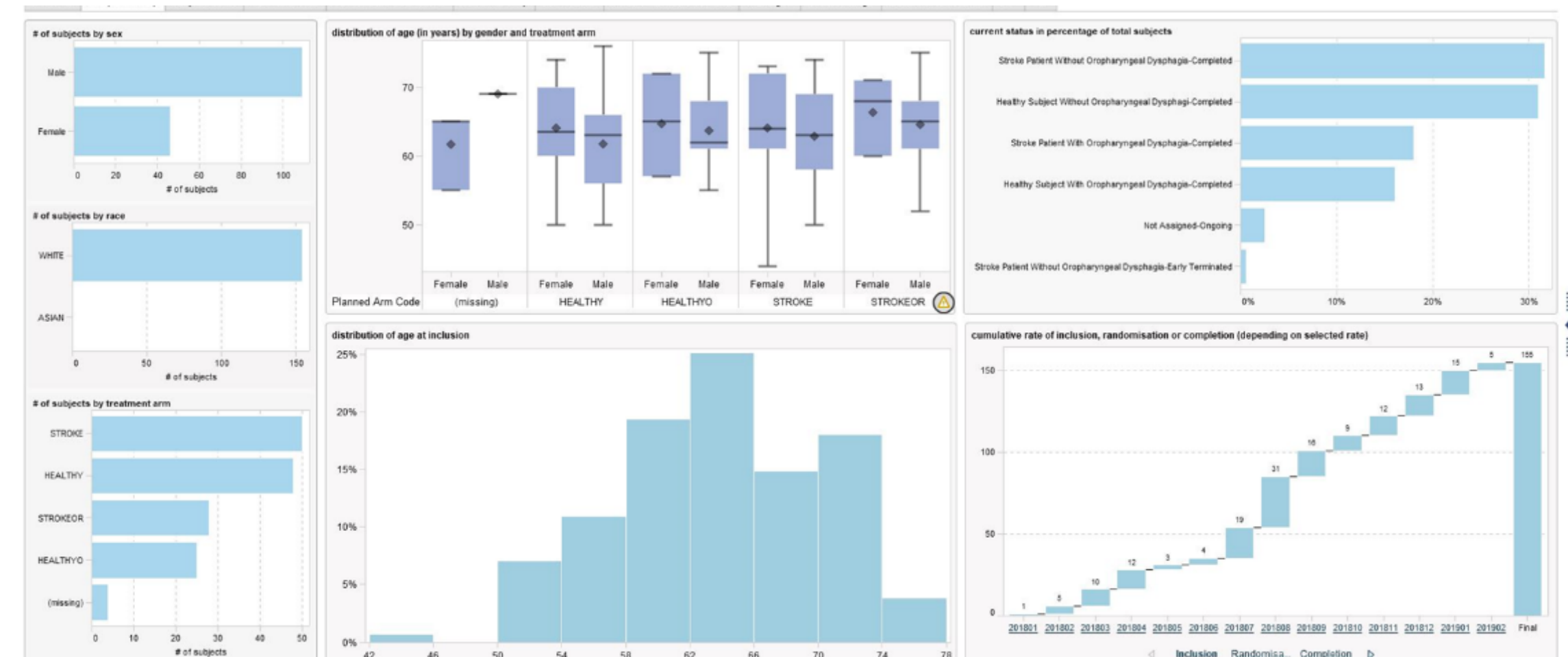


Next steps

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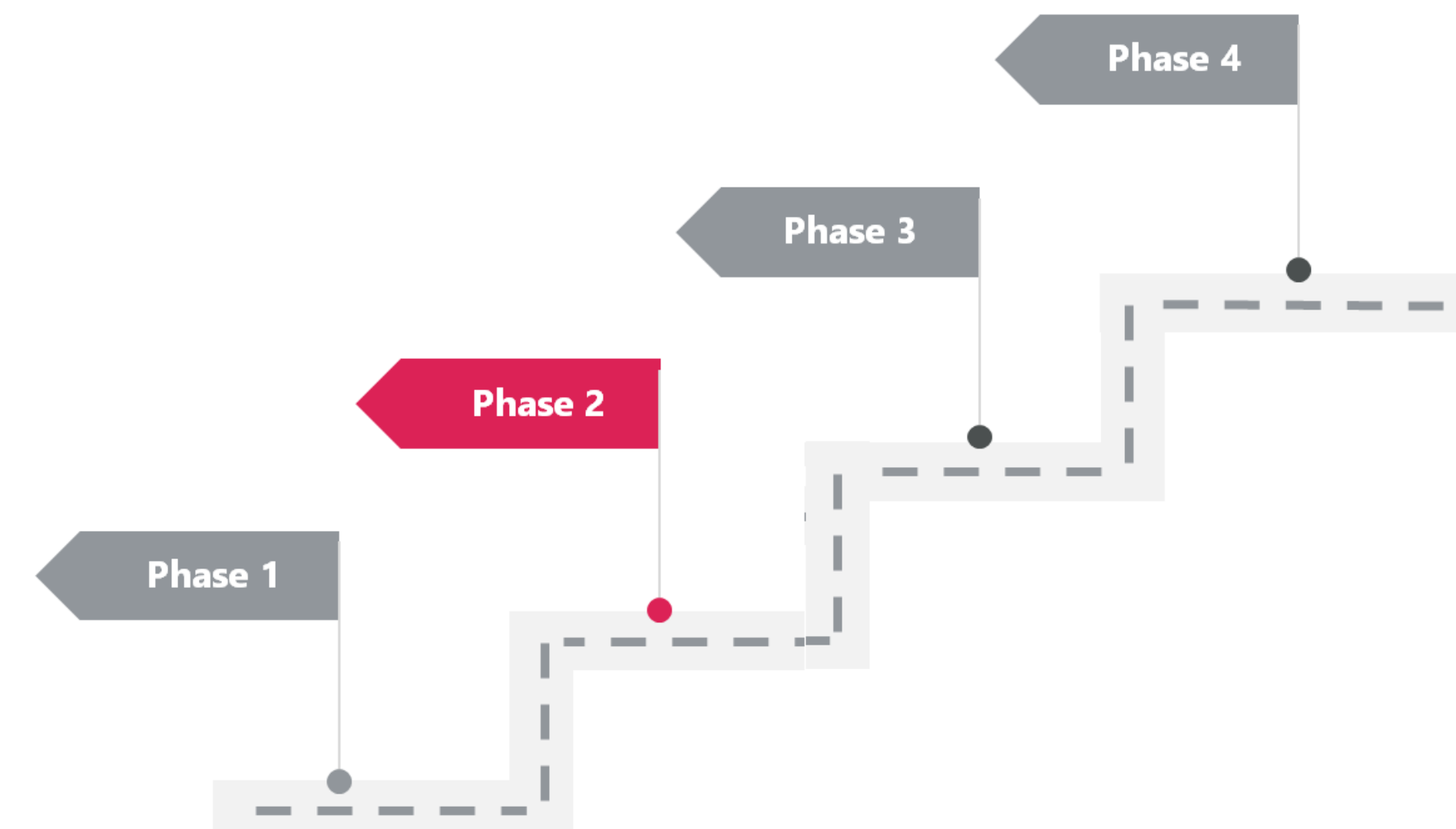
Continue phase I: Maturing

Build on existing products to produce high value and timely insights



Initiate Phase 2: Integration

Connect and collaborate cross discipline (e.g. Computational Biology) for data exchange and visualization



Takeaways



Understanding data

Making data available throughout an organization can be powerful. Employees should know how to use the data properly.

Roadmap-based approach

Every step in the implementation of a solution puts a piece in its place of the bigger picture.

Complexity

Working with various disciplines, combining several techniques and processes comes with complexity and uncertainty.



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