

Norsk medisinsk syklotronsenter AS (NMS)

Lessons learned from Rise with SAP S4H PCE Project at Norsk medisinsk syklotronsenter (NMS)
-June 2022



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Solutions Nordics

Agenda

- 1) Introduction from Norsk medisinsk Syklotronsenter AS (NMS)
- 2) Introduction from NTT DATA Business solution (NDBS)
- 3) The it.lifescience methodology and project approach
- 4) Lessons learned from the ongoing RISE with SAP S4H Private Cloud edition (PCE) project

About NMS (Norsk medisinsk syklotronsenter AS)

- NMS AS is a commercial, non-profit, public-sector company headquartered at Oslo Cancer Centre Innovation Park at Montebello, Oslo, Norway
- The company was established in 2003
- Our owners: Oslo University Hospital (70%), University of Oslo (20%) and Akershus University Hospital (10%)
- Initiated manufacturing of radioisotopes for clinical use in 2006
- Our profits are reinvested into research and development (R&D)
- Headcount of ~43 staff
- We distribute PET-Radiopharmaceuticals across Norway (currently supplying a total of 13 scanners)
- Revenue of approx. €10 mill. in 2021



HQ at OCCI



Manufacturing facility at Gaustad

Infrastructure

1 Cyclotron capable of producing:

- ^{18}F
- ^{15}O
- ^{11}C
- ^{68}Ga

2 Cleanrooms for production of sterile radiopharmaceuticals

- 5 hotcells for GMP-production

R&D/QC-lab + QC-lab

- 4 hotcells
- All equipment required for QC of PET-radiopharmaceuticals

OITL (Oslo Imaging and Therapy Lab)

- Preclinical PET/SPECT/CT scanner
- Equipped with instruments for development, synthesis and characterization of radiotracers



Expansion plans - 2025

- New GMP clean room suite with 2 new clean rooms for asptic production
- New QC-lab
- Clean room for production of radiotherapy products for clinical trials
- New cyclotron



Why do we need an ERP system?

- Our products are very short lived, half life of 110 minutes and shelf live of 10 hours
- The products cannot be stored
- Shipped to nuclear medicine clinics all over the country, by car and by plane
- GMP – compliance
- Products are shipped in quarantine
- Expansion plans: double capacity – up to 6 batches/day

Digitalization and SAP

➤ **Current status of digitalization**

- As many companies within the pharmaceutical industry - relying on paper-based systems
- Avoid digital systems due to very stringent requirements for validation
- Need to replace very cumbersome manual steps in the planning, manufacturing and distribution processes.
- Wish list from the organization for more 10 different individual software solutions
- Recognized the need for a more harmonized and coherent approach - decided to investigate the possibility to set up an ERP system

➤ **Why SAP?**

- Seems to be the ERP-system of choice within the industry. SAP has a rumor of being expensive and more suited towards larger corporations.
- Competitively priced
- In the end - The frequency of updates

Why NTT?

And why did you choose NTT DATA Business Solutions (NDBS) as a partner?

- Prior experience within the Pharma space – dedicated Pharma team, understood the challenges related to radioactive products
- The solution from NTT DATA is industry specific
- Very impressed with the approach taken – difficult for a small company like ours to picture how we would be able to design, set up and validate the system
- I think the new cloud based best practice solution SAP Rise is very suitable for our needs. With less customization, we take a lot of risks out of the equation
- We also like the fact that NTT will be with us also as we move into ongoing operations
- The NDBS team is very professional and supportive. Knowledgeable consultants – understand our needs, positive.
- Have been able to meet face-to-face - has created a very good atmosphere in the project and lowered the barrier for asking “stupid “ questions.

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NTT DATA Business Solutions | Who We Are

NTT Data BS in numbers

1989
founded

15,000+
employees

30+
countries

€1 billion
revenue

Strong background

315,000+
employees

120,000+
employees



NTT DATA

NTT DATA

Experience

30+ years
SAP experience

6,000+
customers in
60+ countries

30,000
Projects,
consulting and
trainings a year

7,000+
consultants trained
and enabled
around the world

500+
SAP S/4HANA
projects

5,100
Managed Services
engagements

Leading SAP Partner



NTT DATA Business Solutions | Selected Customer References

S/4HANA NNN or Greenfield	S/4HANA Conversion (Factory Approach)	S/4HANA Cloud (SaaS)	HANA Platform				
					 DANFOSS IXA		
							
							
							
							
							

NTT DATA Business Solutions | Selected Customer References Lifescience

Santa  Farma


Biofarma

 PRESSPART


VETTER

octapharma®


Eisai

 **STERLING**
Pharmaceutical Services, LLC

 **RAUMEDIC**
— Lifeline to Health —


ALK

 **Lundbeck** 

 Sanquin


SAISON
INFORMATION
SYSTEMS
CO., LTD.

 **aspen**
HOLDINGS


Synthon

 **CardinalHealth**


fertin
Pharma


beaphar®


Hisamitsu

 **Bilthoven Biologicals**
Cyrus Poonawalla Group


BIONTECH


CENTRIENT
Pharmaceuticals


Santen

 **PLASMA
INDUSTRIES**
BELGIUM


TAISHO PHARMACEUTICAL

 **AJVaccines**

 **BASF**
We create chemistry

 **genzyme**
A SANOFI COMPANY


Perrigo®


UPSA

 **GW**
pharmaceuticals

 **MARTINDALE PHARMA®**
Making lives better

 **exact
sciences**

 **Jazz Pharmaceuticals**

 **Bionorica®**

 **GCBT**


LABORIE

 **Lundbeck** 

 **APOTEX**


Recipharm
good for business

 **Sera Scandia**

 **MSD**
Animal Health

 **DAINIPPON
SUMITOMO
PHARMA**

it.lifesciences methodology

Tailored Methodology

- Based on GAMP5 (for Pharma) and SAP Activate methodologies
- Integrating implementation and computer system validation

SAP Qualified Partner Package

- Using structured business process model (BPML)
- The template Supports 300+ processes and over 1.500 requirements.
- Industry specific enhancements
- Integrates with most common used systems in the industry (LIMS, QMS, etc.)

Real Tools & Templates

- Solution Manager 7.2 is used for end-to-end project support
- Containing all project management and template deliverables
- Real reusable deliverables (IP) and SAP accelerators

Uniquely Skilled Consultants

- Implementing best practices is no 'trick', it is an 'art' (best practice)
- Merely understanding SAP is not good enough in Life Sciences (SAP+)
- Speaking the customer language is essential (industry).
- Understanding the impact of risk management and validation is critical (CSV)

A structured method for green field implementations and roll-outs

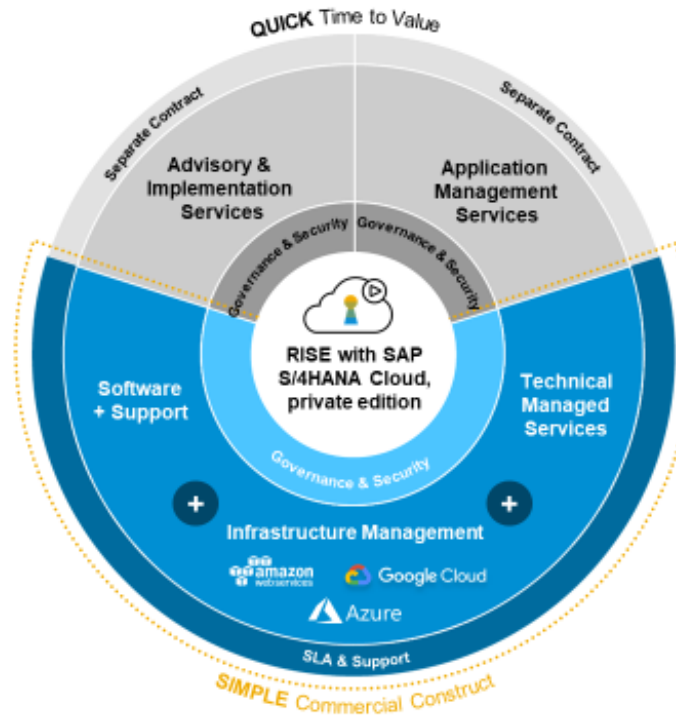
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Lessons Learned

RISE with SAP S4H Private Cloud

A simple and attractive **full-subscription offering** with the best of all worlds



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SAP

- SAP S/4HANA Software
- SAP Enterprise Support
- Technical Operations

Service Partners

- Application Managed Services
- System Conversions
- Business Transformation

Hyperscaler

- Low TCO
- High Availability
- High Scalability

Enablement assets on RISE with SAP S/4HANA Cloud

RISE with SAP S/4HANA Cloud, Private Edition



What is RISE with SAP?

RISE with SAP is an offering that brings together capabilities and services you need to transform your business in the way that works best for you. [Check out this video](#) to learn more.

[Learn More](#)



Onboarding Webcasts

Discover ways to streamline the system provisioning and setup process for RISE with SAP. Benefit from guidance regarding informational requirements to access your system, learn about support options, and get answers to your questions to get started.

[Learn More](#)



SAP Enterprise Support Academy

Expand your digital skills on your journey to RISE with SAP easily through the [SAP Enterprise Support Academy](#). Join the new e-learning to get enabled to start your SAP S/4HANA Cloud, private edition implementation, as part of the RISE with SAP offering.

[Learn More](#)

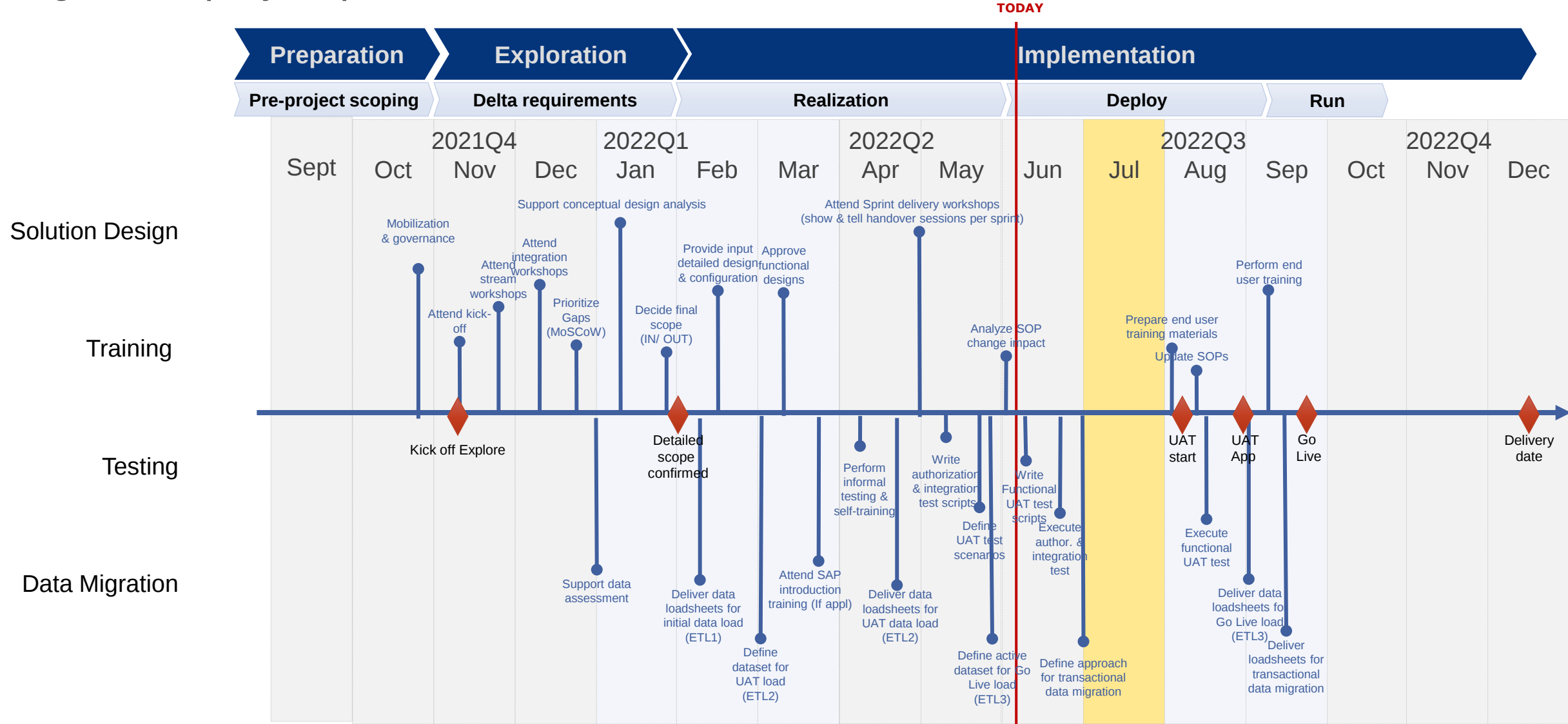


Learning Journey

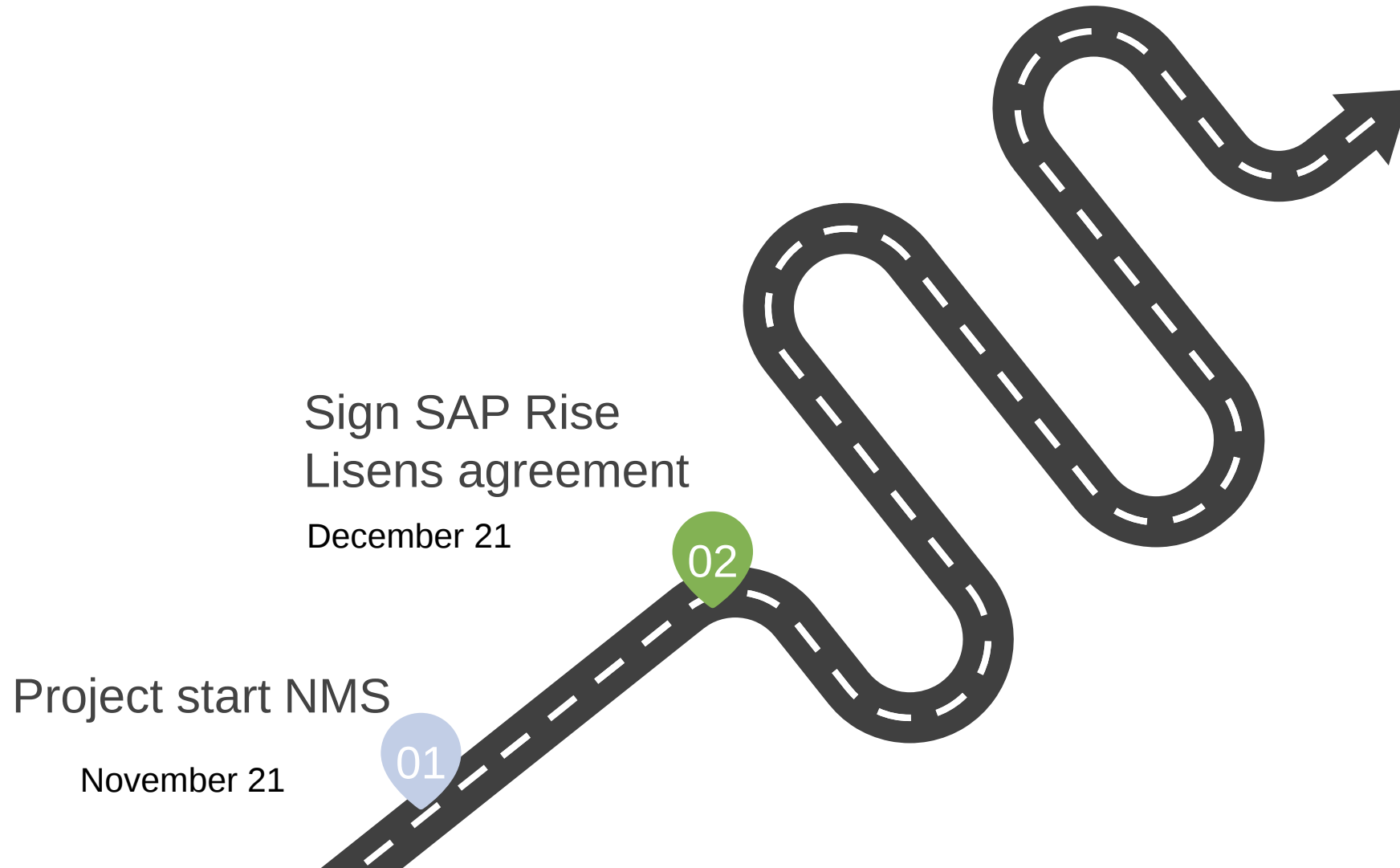
Jump-start your learning with solution-specific SAP Learning Journeys focused on common use cases designed to help you navigate the path to success with RISE with SAP.

[Learn More](#)

High level project plan

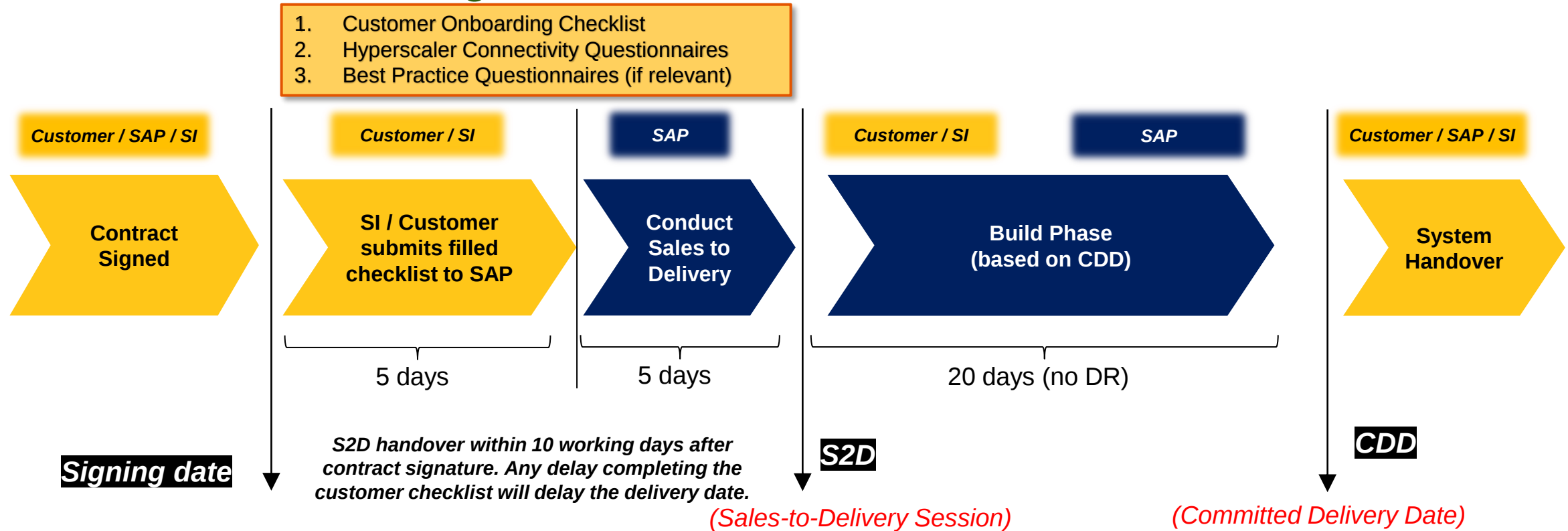


Lessons learned RISE with SAP S4H PCE



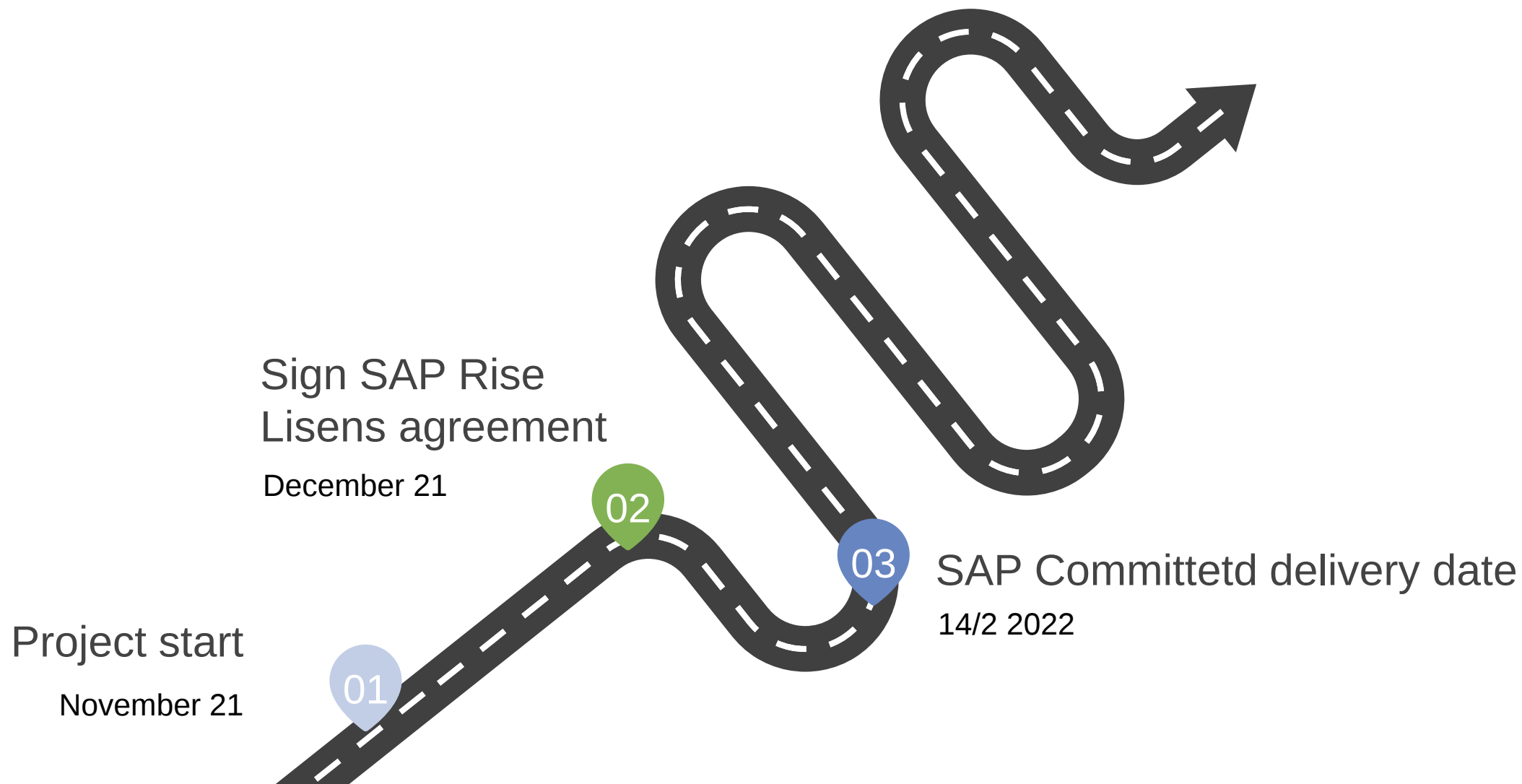


Timeline overview for 'greenfield' Azure



- Changes to the BOM or additional requirements might affect the timeline
- If the system integrator (SI) believes that the customer needs additional time to complete the questionnaire, they should choose a later delivery date
- The timelines are provided in business days and exclude weekends and holidays
- This timeline is based on a standard build timeline, **10 days increase with DR**, if any of the following is required during the initial build, it will have a longer delivery timeline: **Best Practices content activation / GxP (10 days)**

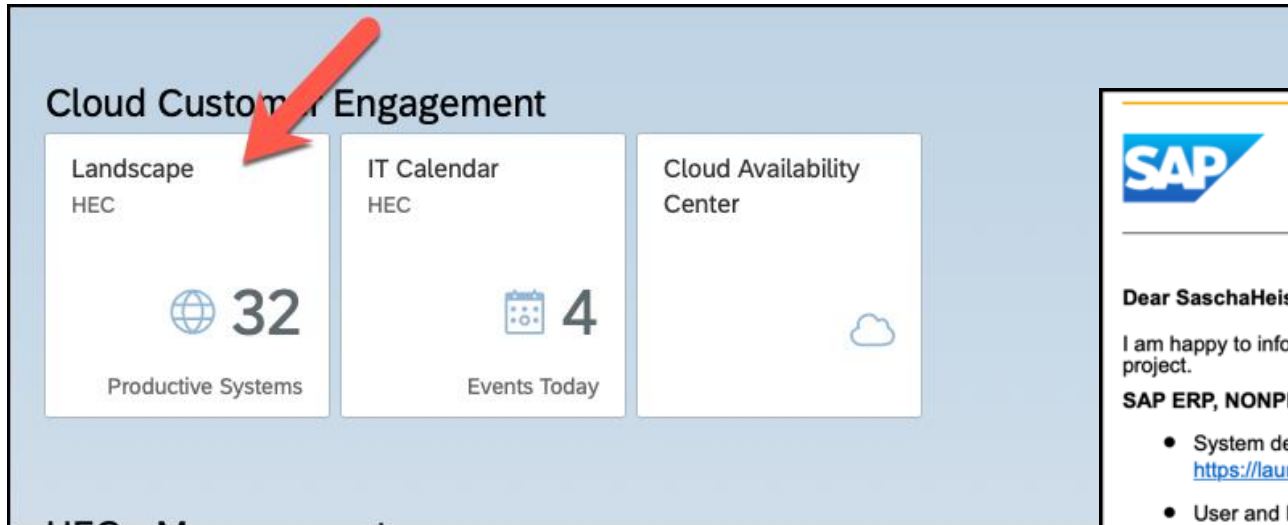
Lessons learned RISE with SAP S4H PCE



Systems Handover / Delivery

Launch Pad Access

Launch Pad System Information



- Handover notification has been sent via email.
- Handover detailed information will be accessible in the SAP Launch pad
- Admin User ID's and Password sent under a separate link to a secure OneDrive folder.

Notification Email Sample

**HEC Delivery**
Landscape Status Change Notification - HEC int - MCD VLAB Corp4 XS

Dear SaschaHeise,

I am happy to inform you that the system mentioned below has been turned over and is now available for use in your project.

SAP ERP, NONPROD X4U

- System details can be seen in the ONE Support Launchpad using this link:
<https://launchpad.support.sap.com/#/hec/landscape/system/000000000500106794>
- User and Password for initial logon will be provided to you in a secure way

According to your Statement of Work (SOW), you are requested to confirm the delivery of all contracted landscapes and solutions **within 5 working days**. Therefore, I kindly ask you to confirm that the above mentioned system has been delivered to you, using this link:

[click to navigate to CONFIRMATION app](#)

In case we do not receive any feedback from you within this time frame, we consider the handed over system as accepted.
Should you have any questions or concerns, please do not hesitate to call me directly.
I am happy to provide you more details.

Thank you in advance for your confirmation and acknowledgement.

Best regards,

Sascha Heise
SAP HANA ENTERPRISE CLOUD

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SAP SE, Dietmar-Hopp-Allee 16, 69190 Walldorf, Germany

ECS – S/4 HANA PCE Only - Roles Names

Key Customer Facing Roles	Responsibilities
<u>Client Delivery Manager</u>	▪ Primary point of contact for ongoing service and support requirements of the customer. ▪ Ensures regular weekly operations and service sync meetings with the customer throughout the duration of the SAP HEC contract. ▪ Contract administration and operational change management. ▪ Escalation Management during operational run phase. ▪ Conduct Customer Kick off call
<u>Project Lead</u>	▪ Primarily responsible for managing the HEC project activities during the customers' lifecycle in HEC ▪ Coordinates with Customer Project Team (Customer & SI) and the extended SAP teams to align project information, requirements and rollout timelines. ▪ Technical planning of major Customer upgrades ▪ Escalation Management during planned project activities
<u>Technical Service Manager</u>	▪ Primary technical contact for all technical and infrastructure related topics ▪ Leads and advise HEC technical teams regarding Service Delivery ▪ Supports the customer technical queries ▪ Act as the technical single point of contact during the de-escalation process
<u>Cloud Architect & Advisor</u>	▪ Works along side Sales to present solution to Customer. ▪ Trusted Advisor to customer ▪ Architect solution for customer ▪ Defines Technical Qualification and Assessment ▪ Supports change request process

ECS Kick off Session from SAP

Agenda

- Handover / Delivered System
- Service Level Agreements
- Support Channels and Raising Tickets
- Customer Q & A

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Agenda

- Roles & Responsibilities
- Security Patches
- Customer Q & A

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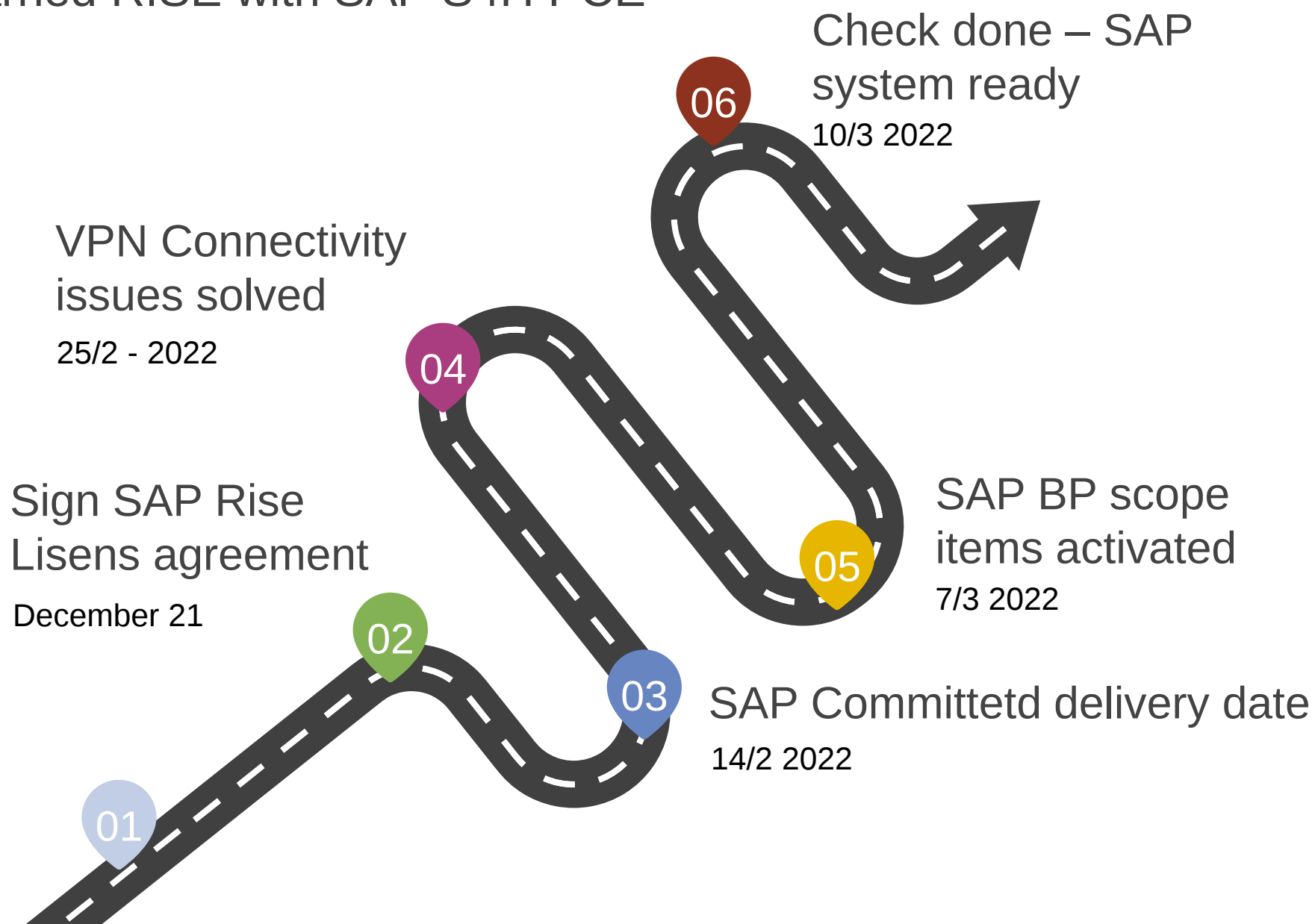
- SAP PCE Service Reports and Meeting
- Contract Change Request Process
- Customer Q & A

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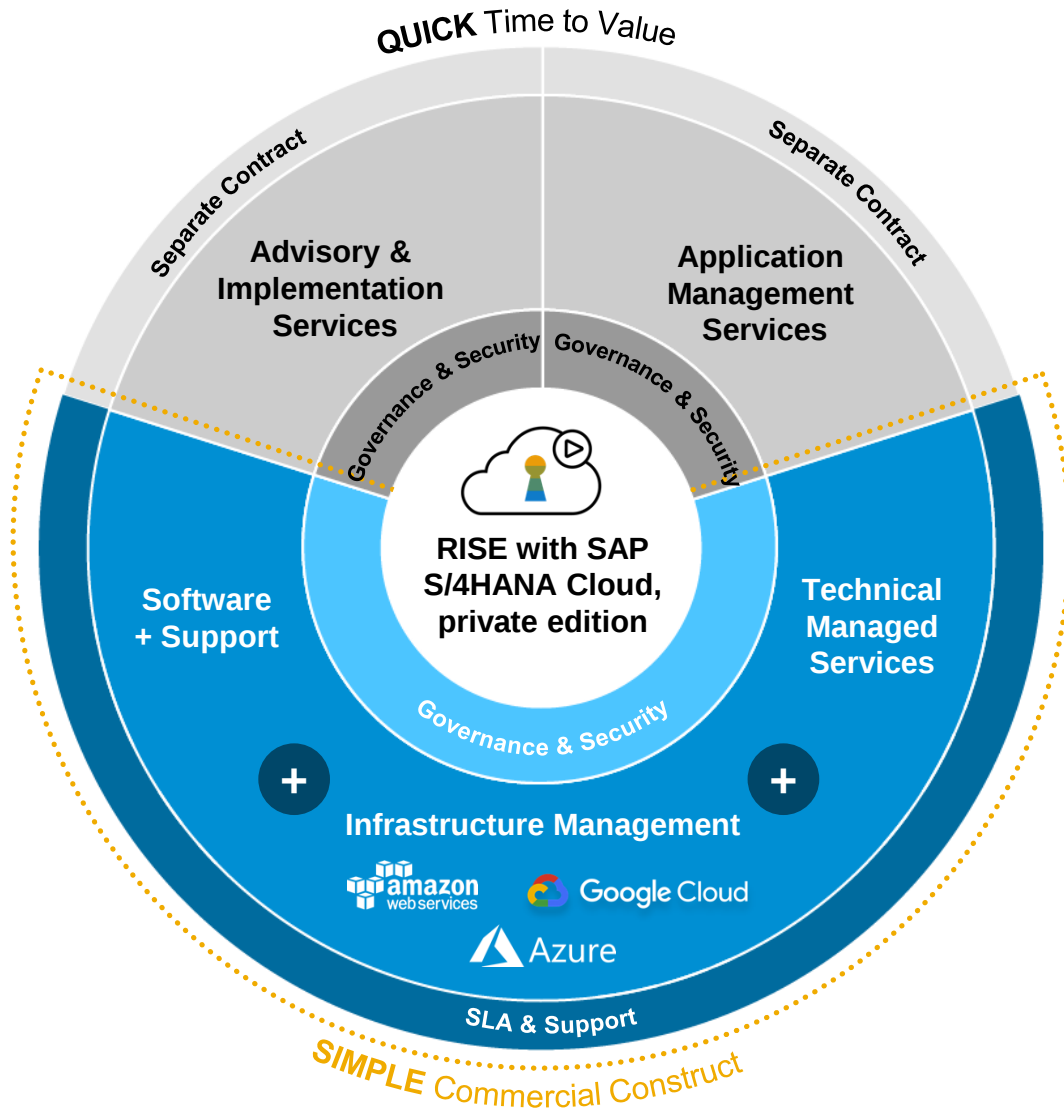
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Lessons learned RISE with SAP S4H PCE

Project start
November 21



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SAP

- SAP S/4HANA Software
- SAP Enterprise Support
- Technical Operations

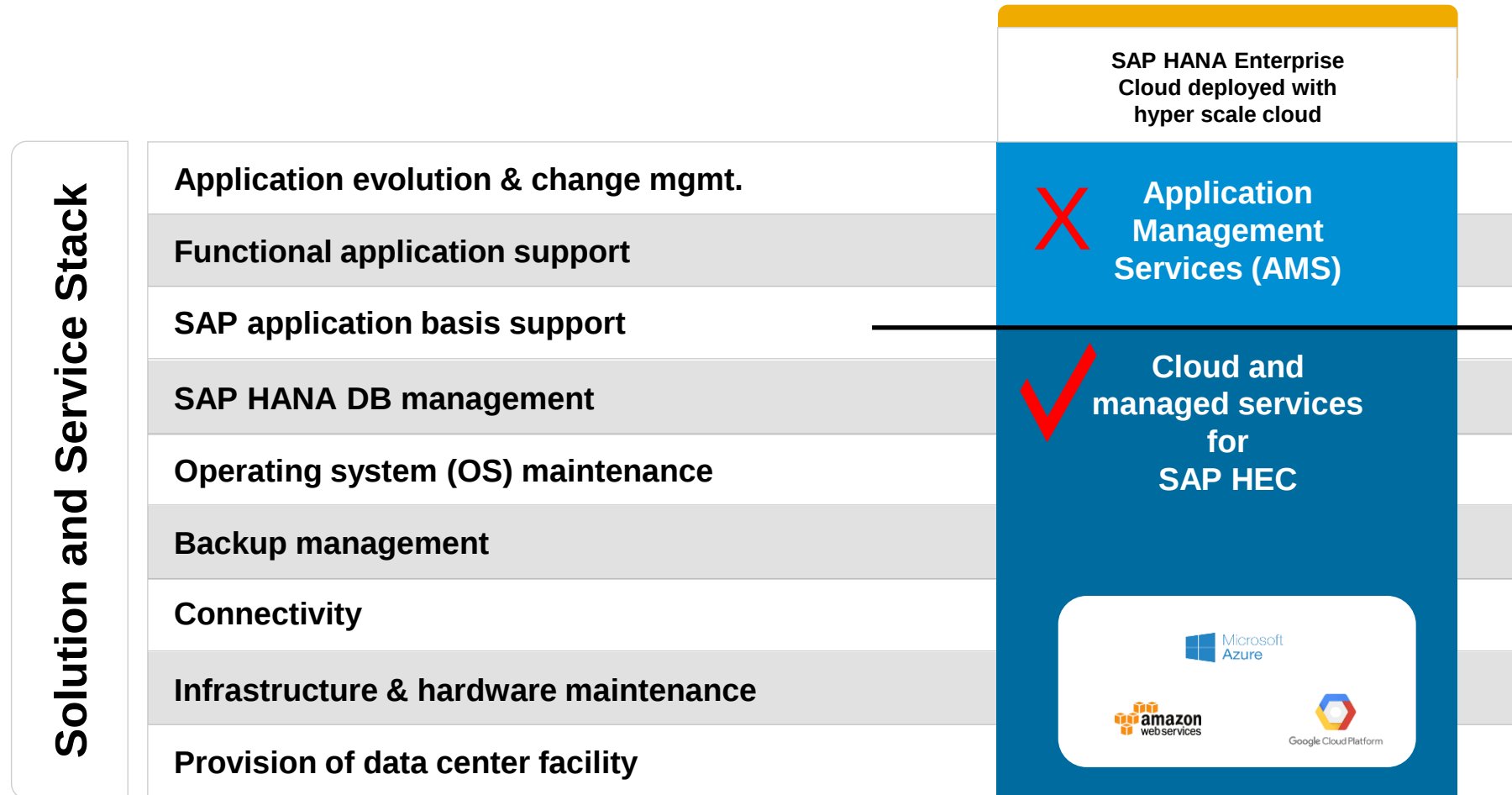
Service Partners

- Application Managed Services
- System Conversions
- Business Transformation

Hyperscaler

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SAP Enterprise Cloud Services – how these can provide full coverage



Benefits:

- SAP full accountability
- Integrated monitoring (infra to application)
- Multi-cloud deployment models
- Access to SAP innovation roadmap releases

Technical Services - Roles and Responsibilities (R&R) Matrix

Solution and Service Stack	Application Evolution and Change Management	Cloud Application Services (CAS)
	Functional Application Support	Cloud Application Services (CAS)
	SAP Application Basis Support	
	SAP HANA DB Management	SAP ECS (Standard and Optional)
	Operating System (OS) Maintenance	
	Backup Management	
	Connectivity	
	Infrastructure & Hardware Maintenance	
	Data Center Facility and Provisioning	

- A comprehensive list of infrastructure and technical services – the [ECS Roles and Responsibilities](#)
- Private Cloud Edition PCE.
- Familiarize with this to understand how SAP can help in the successful implementation and administration of your SAP systems.
- You can use it as a reference for any future requests.

[RISE with SAP S/4HANA Cloud, Private Edition and SAP ERP, PCE](#)



Roles and Responsibilities Matrix Categories

The “Roles and Responsibilities Matrix” specifies who is responsible for carrying out related activities – SAP or Customer. Customer’s activities can be done by customer’s SAP Team or the customer engaged SI.

Standard Services

All tasks/services that are included as part of the standard Services, covered by the Service Fee and performed by SAP, as applicable to customer

Optional Services

These tasks/services are not covered in the standard Services, and are not and cannot be covered by the Cloud Application Services

These tasks/services may be elected by customer; are subject to additional service fees; must be specifically contracted for and itemized in the customer’s contract (original contract or via a change request) and can only be performed by SAP.

CAS – can be performed by customer

Can be performed by customer: Include tasks/services that a customer can perform, but the customer may elect to have SAP to deliver

Additional Services

Include one-off tasks/services which are not covered by Standard, Optional and/or Cloud Application Services.

These tasks/services may be elected by customer; are subject to additional service fees; can only be performed by SAP.

Excluded Tasks

Those tasks/services that can only be performed by the customer and are excluded from Standard Services, Optional Services, Additional Services and/or Cloud Application Services

➔ The complete list can be found in the [R&R Document](#)

Key take-aways

- 1) Do your enablement on SAP RISE S4H PCE
 - 1) Onboarding webcasts
 - 2) Learning journeys
- 2) Proactive participation from customer in the sales and scoping phase
- 3) Familiarize yourself with the Roles and Responsibilities Matrix from SAP
- 4) Be aware of the lead time for Services from SAP – this will affect your project plan
- 5) Follow-up and have a close communication with SAP during system build
- 6) Kick-off sessions with SAP after system handover and execute regular ECS meetings
- 7) Don't underestimate the need for your own SAP Basis support

Thank you!

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