

DH01

AstraZeneca Early Clinical Biometrics Journey into Integrated Clinical Data Environment

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KAP Europa
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EU 2018

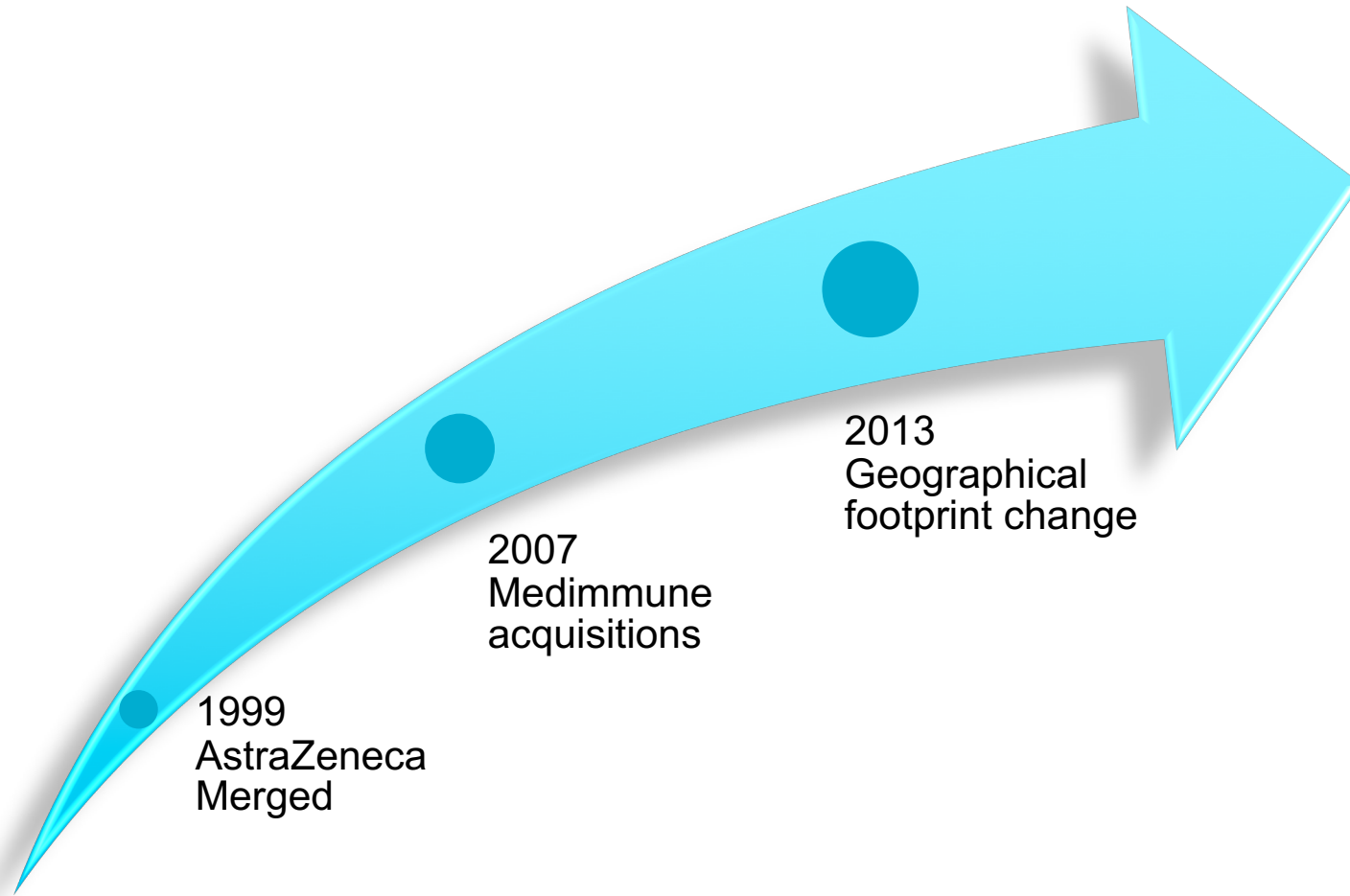
The Clinical Data
Science Conference



Agenda

- **Introduction**
- **What is AstraZeneca Integrated Clinical Data Environment (AZ-ICDE)?**
- **Early Clinical Development (ECD) Journey into AZ-ICDE Implementation**
- **Conclusion**
- **Acknowledgement**
- **Questions**

Introduction



- Historically, different (A&R) system across its early and late phase science units.
- Efficient R&D clinical collaboration needed
- 2014 a vision of one single platform storing and reporting clinical data was endorsed.

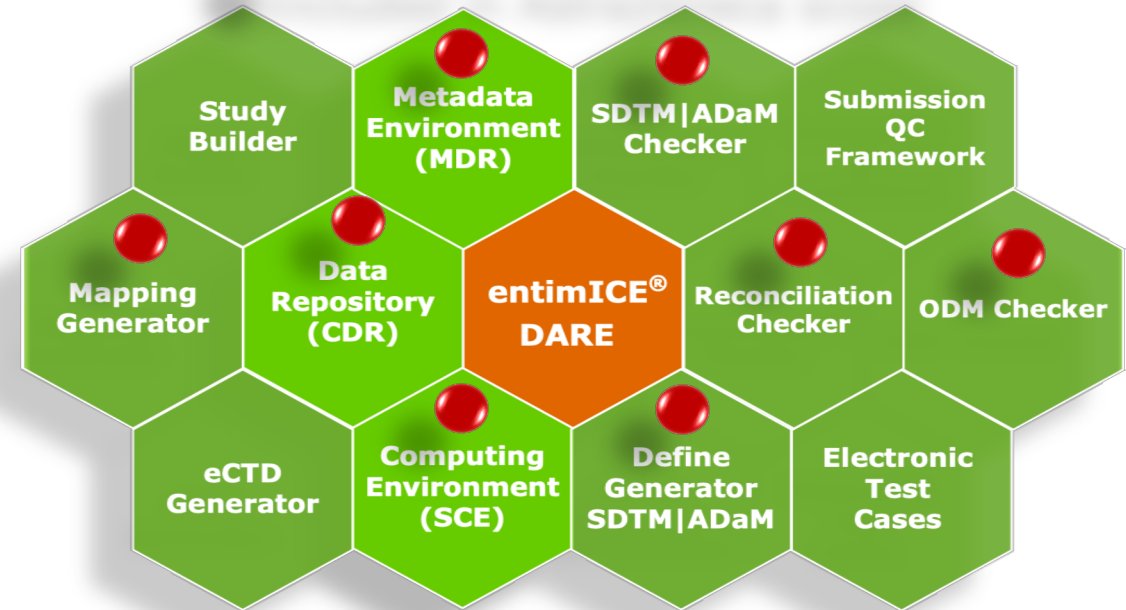


What is AZ-ICDE?

- Clinical study data storage and analysis reporting environment
- Developed by Entimo AG (Berlin, Germany)
- Configured and hosted for AstraZeneca by nnIT (Søborg, Denmark)

AstraZeneca Integrated Clinical Data Environment (AZ-ICDE)

● Included in AstraZeneca scope



INTEGRATION

SAS® Grid

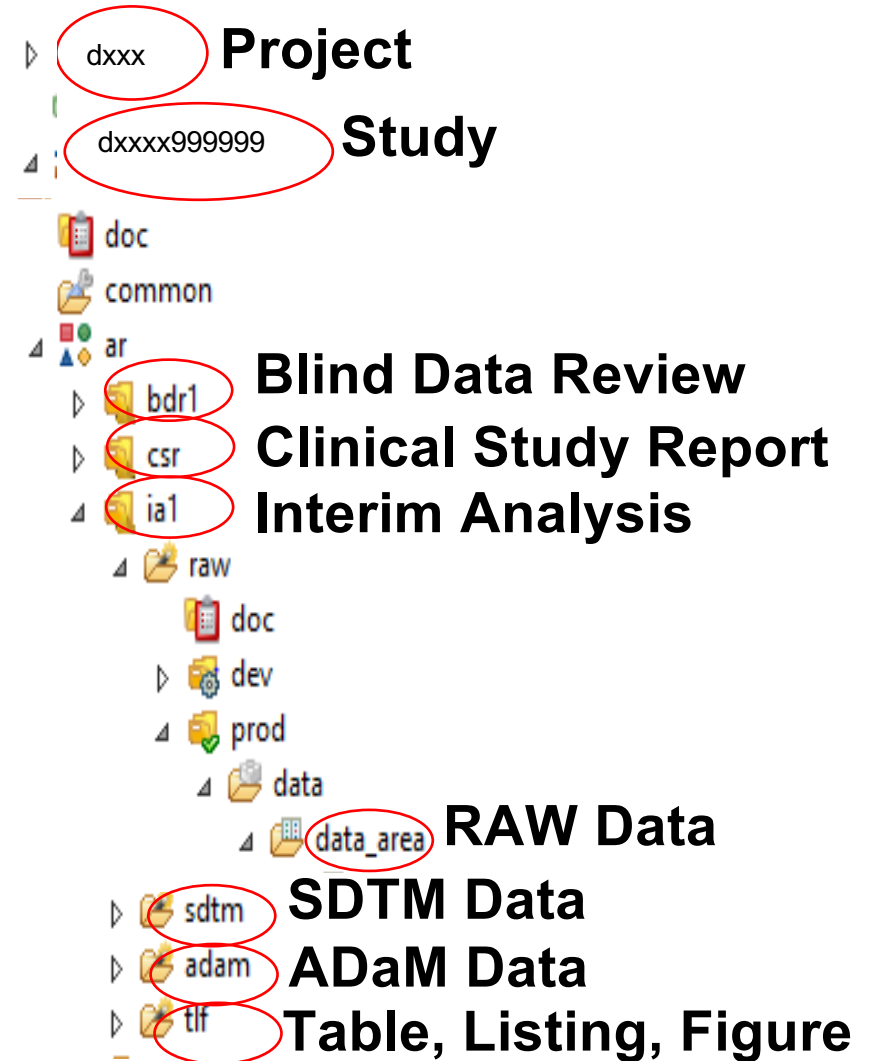
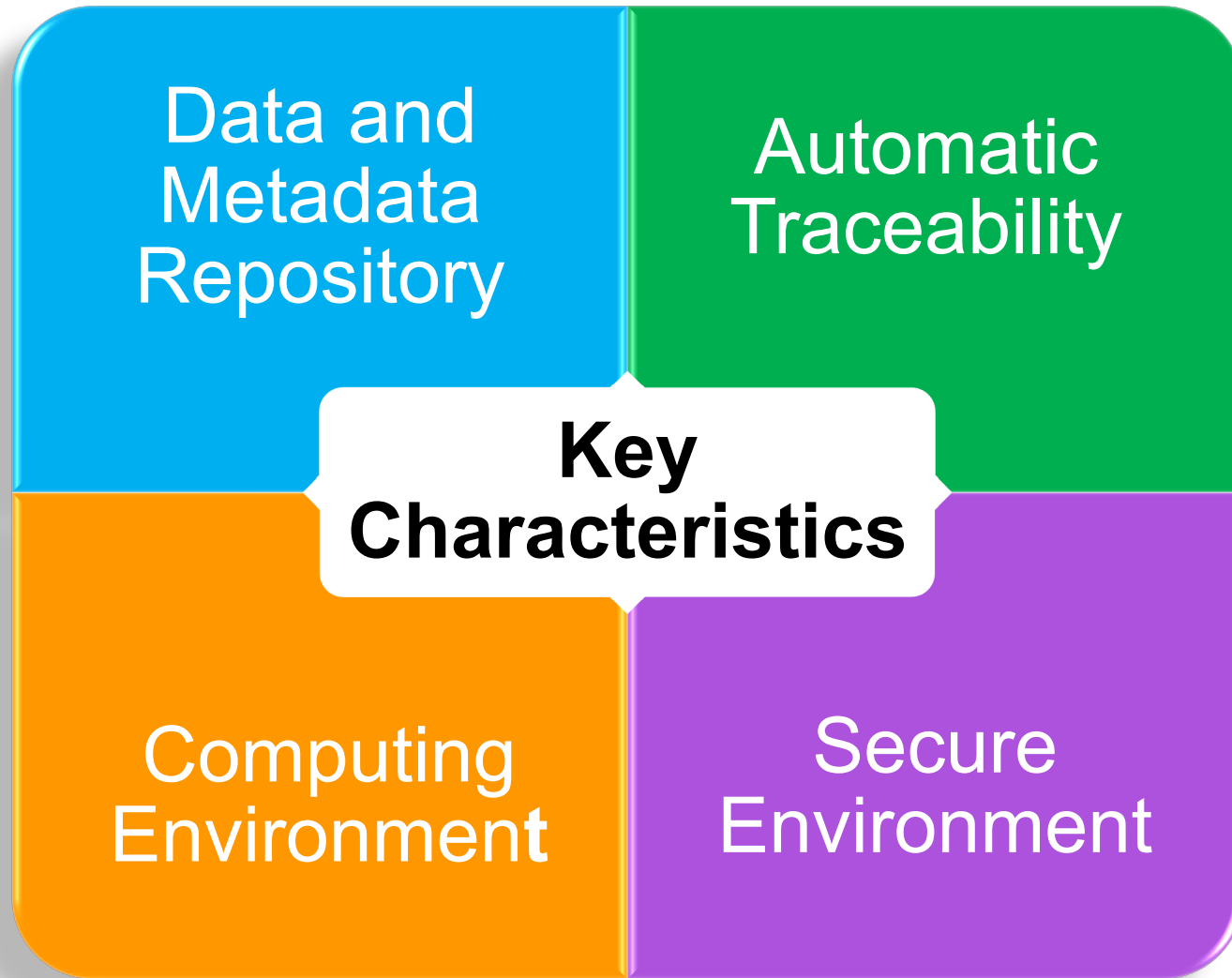
Realtime data
Visualisation

PDF Builder

Network
file shares

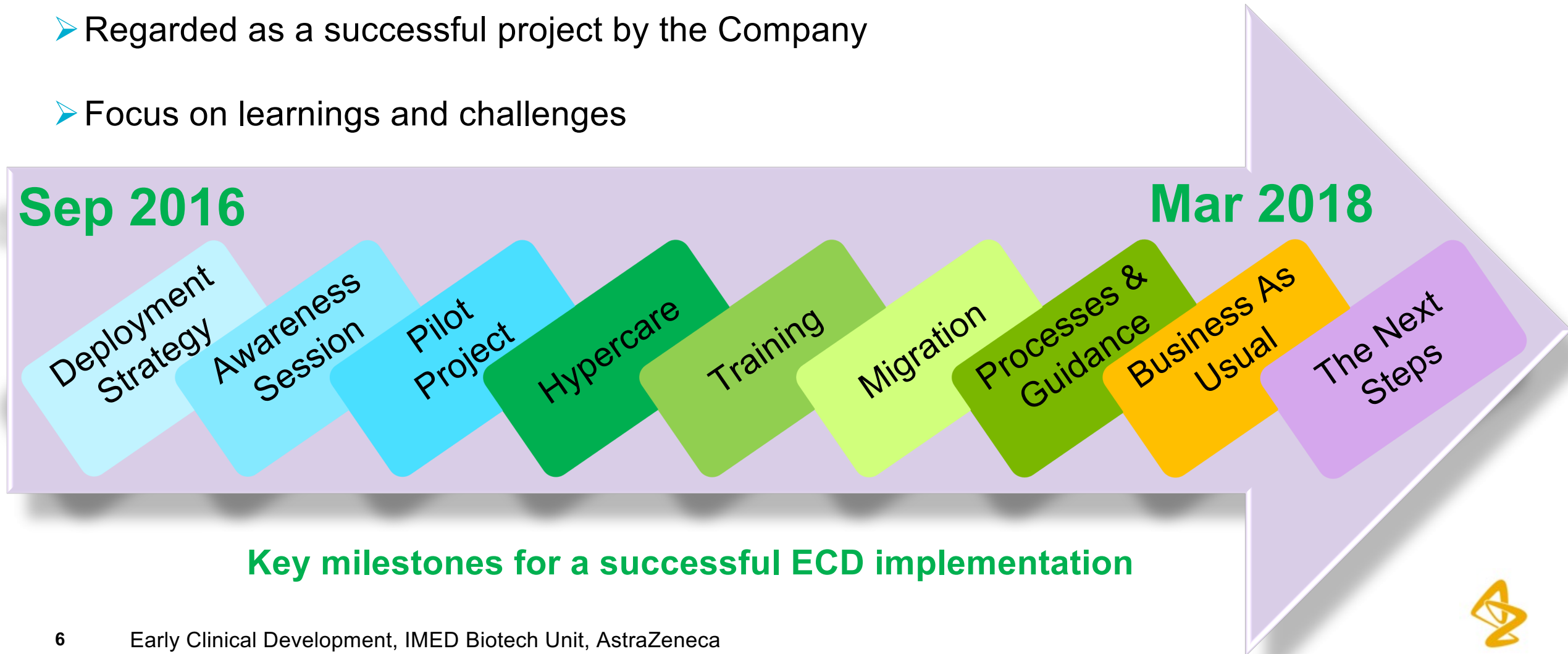


What is AZ-ICDE?



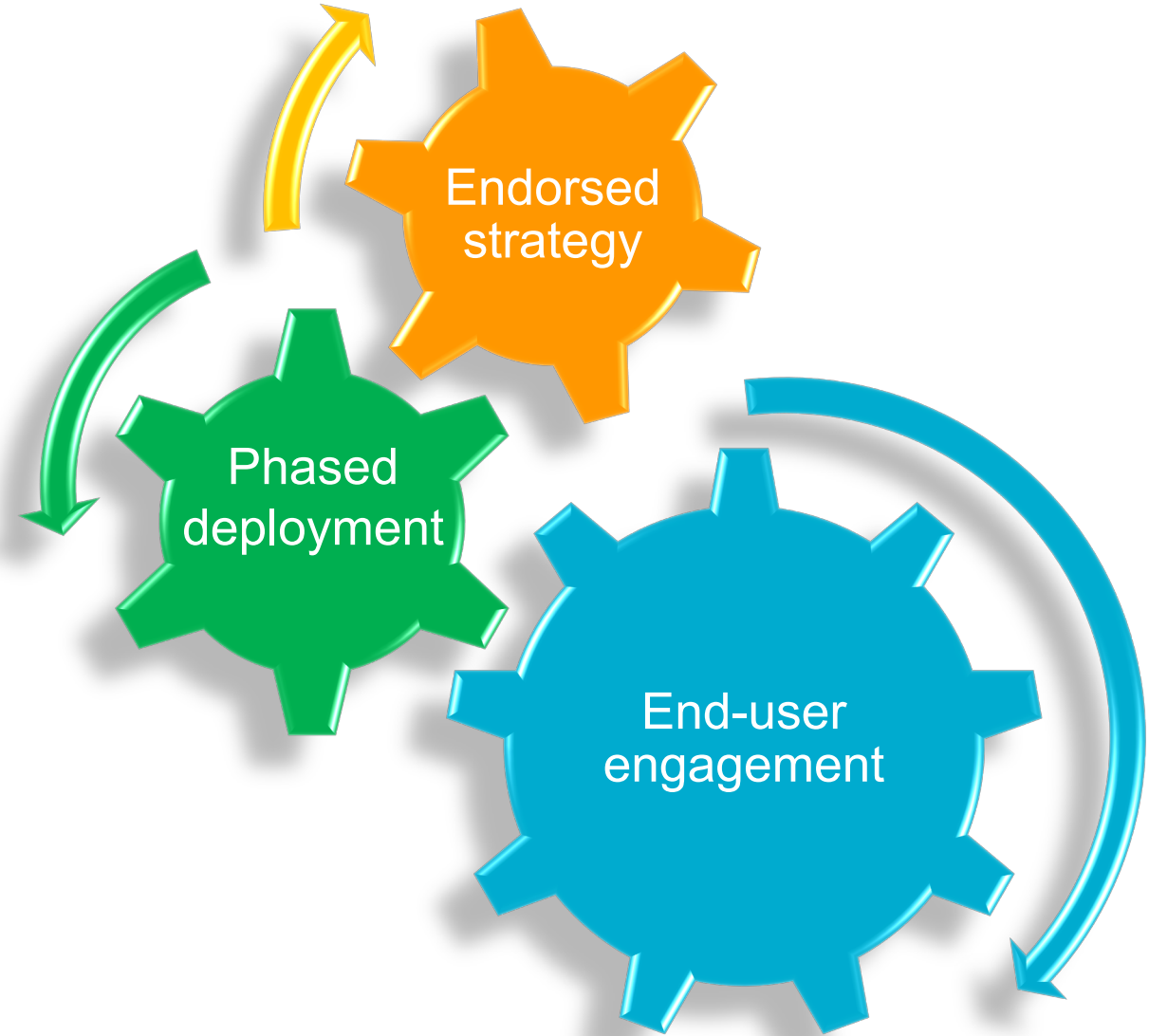
ECD Journey into AZ-ICDE Implementation

- Internal Programme - collaboration among AstraZeneca (AZ) science units
- Regarded as a successful project by the Company
- Focus on learnings and challenges

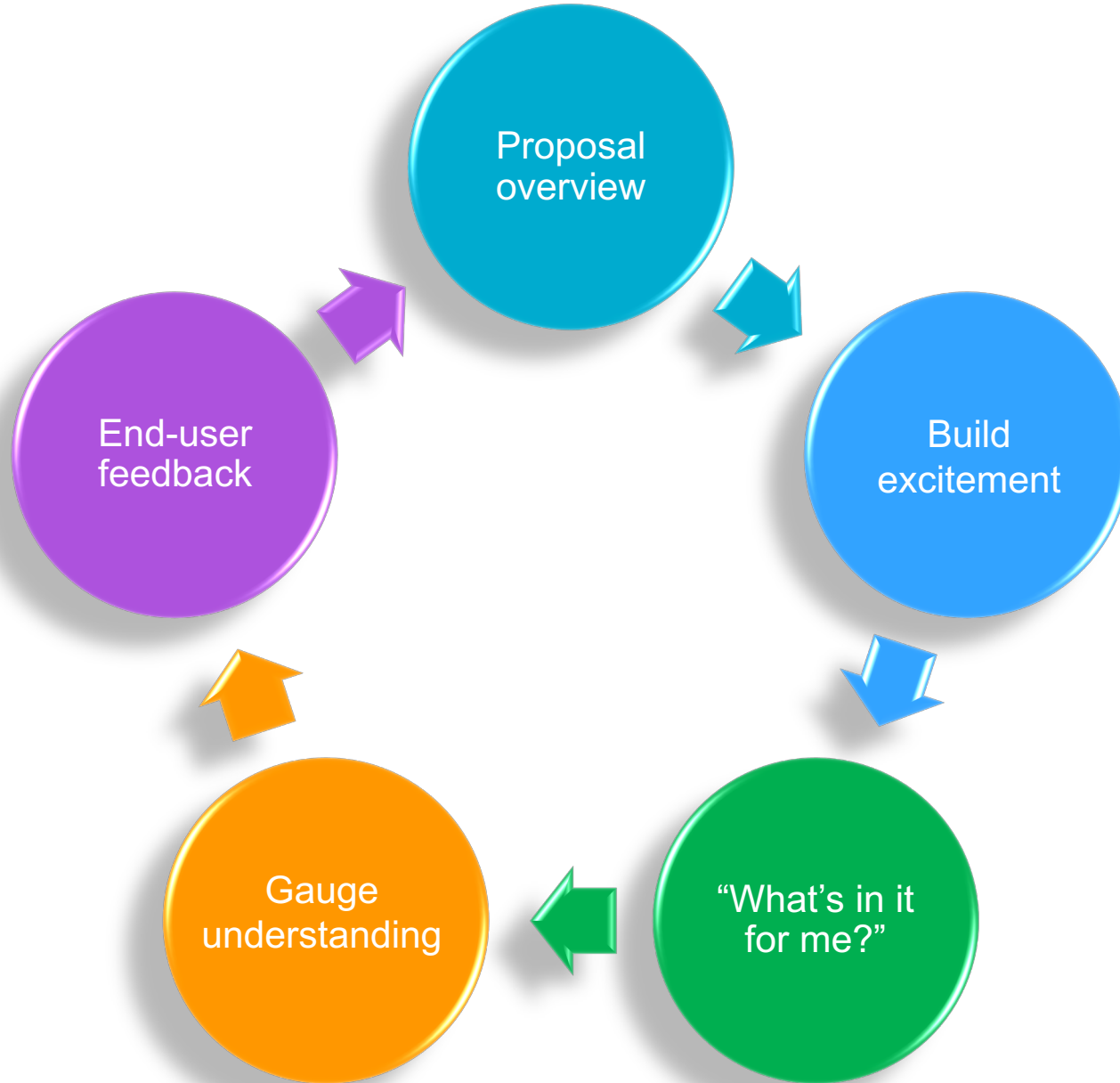


Deployment Strategy

- Endorsed strategy tailored for the ECD needs
- SAS GRID and entimICE-AZ phase deployment safeguarding deliveries
- Interactions with the user community critical for platform acceptance



Awareness Session



- End users felt listened to and could influence
- Setting measurable expectations from end-users
- Do not underestimate the need for user engagement and interactions for system acceptance!



Pilot Project

Selection criteria

- Low risk projects
- Regulatory deliverables between Apr and Oct 2017
- Have a contingency plan

Outcome

- Gain in-depth knowledge on new A&R system
- Lessons learnt used to develop processes & guidance
- Help estimate resources for future projects



Hypercare

Aim

- Dedicated team to provide end-user support & training
- Representatives from implementation team and biometrics functions
- Advocates for the new system

Benefits

- Weekly drop-in clinic and ad-hoc training
- Develop new processes & guidance
- One-to-one user support as necessary

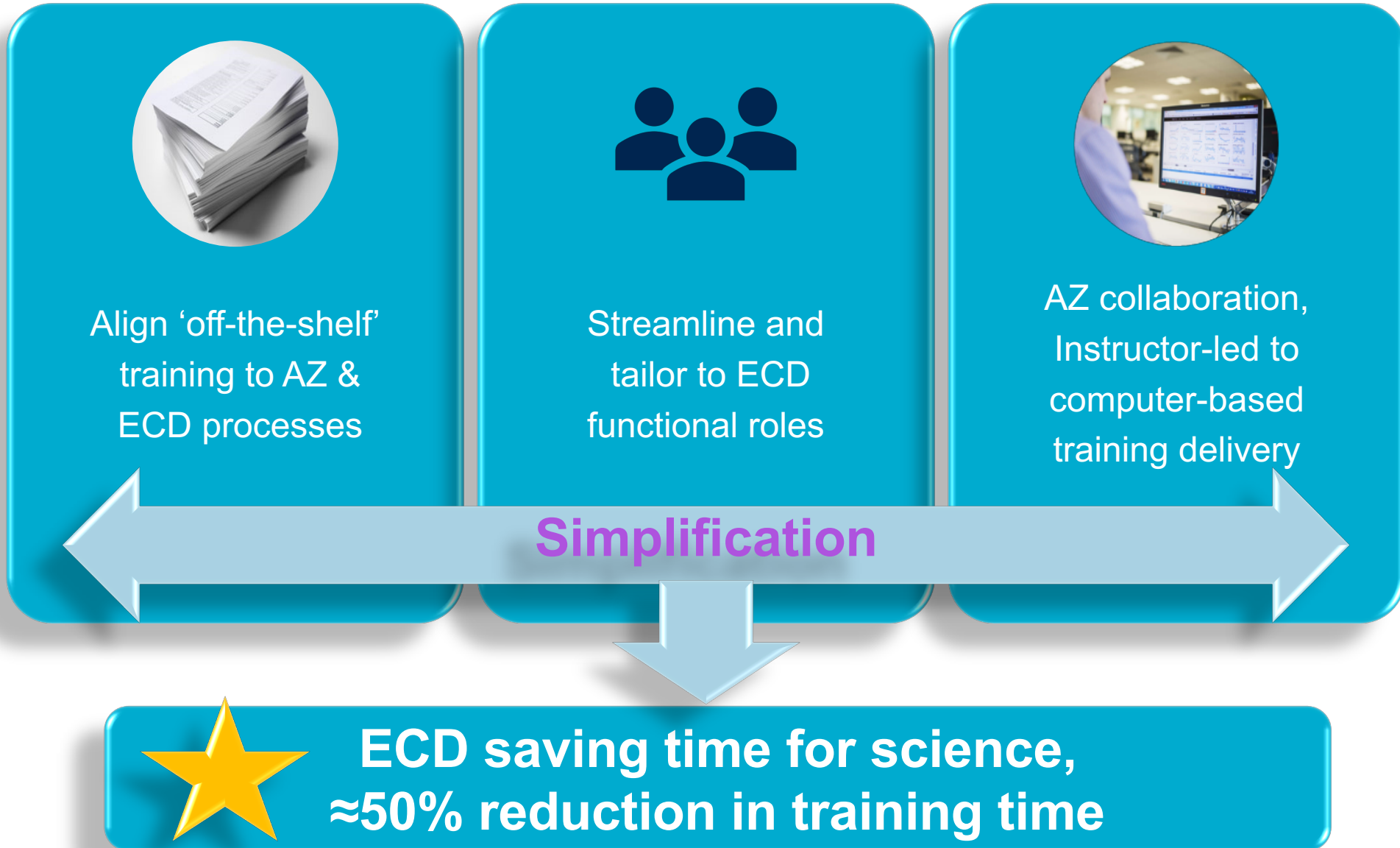
Challenges

- Limited knowledge on the new A&R system
- Resources stretched at times
- A&R implementation in ECD for the first time

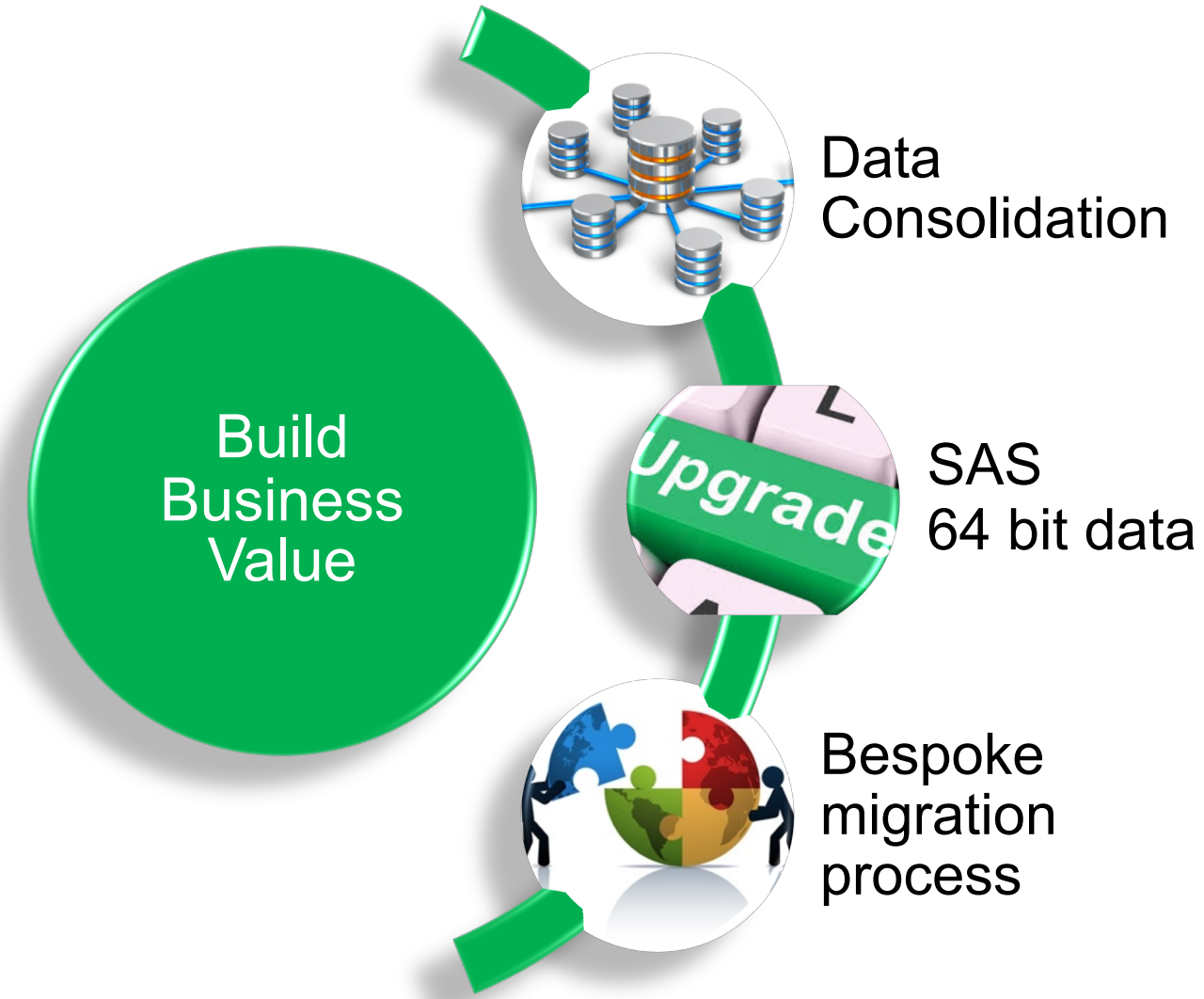


Training

Training is Mandatory to have access to AZ-ICDE



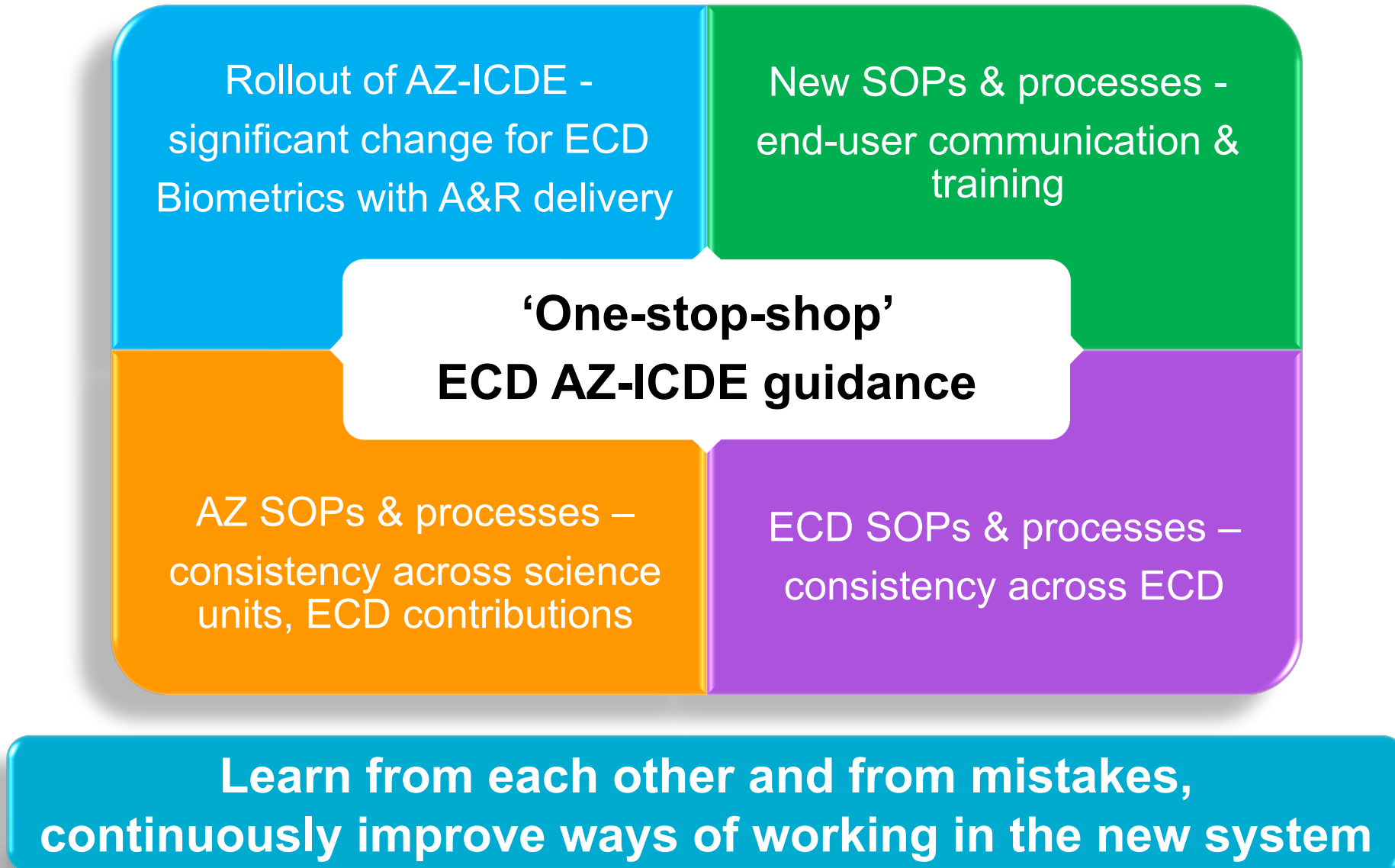
Migration



- An efficient process optimised for the business
- Cooperation with drug project team studies requiring migration support
- Collaboration with vendors on dataflow changes



Processes & Guidance



Business As Usual

Aim

- Deployment to Business As Usual (BAU) transition
- Develop ECD based Subject Matter Expert (SME) community
- Collaborate with AZ SMEs

Benefits

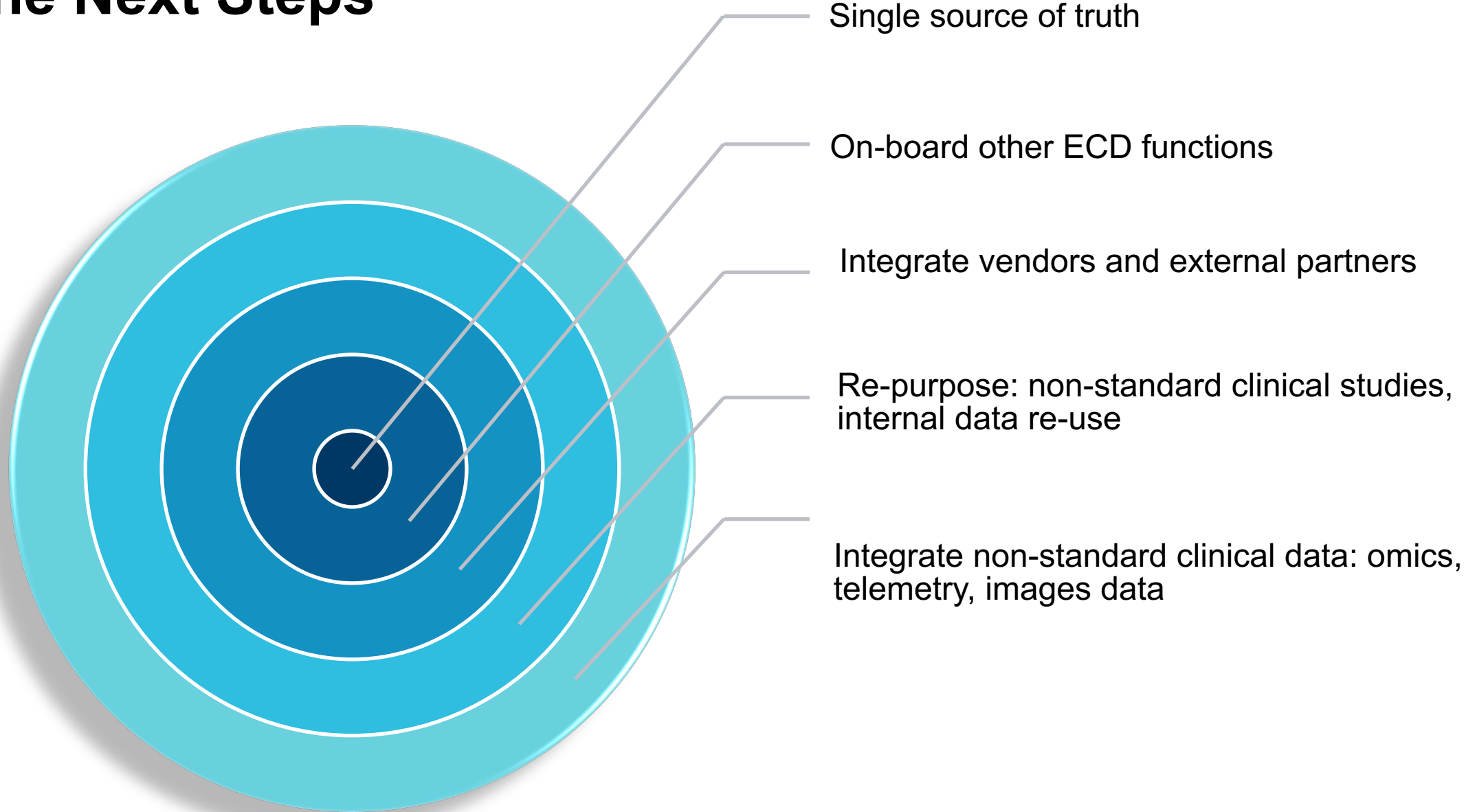
- Location based SME (Sweden, UK, US)
- Provide end-user support and ad-hoc training
- Contribute to processes & guidance

Challenges

- Knowledge and experience on the new system
- Resource allocation for and drug project priority
- Scope of SME role



The Next Steps



Conclusion

Design and Strategy

- Early engagement from business in the system design
- A deployment strategy unique for you
- A simplified and step-wise introduction

User engagement

- Active end-user engagement
- Dedicated support team
- Efficient training and clear processes.



Most importantly it's about the journey and bringing everyone along with you!



Acknowledgement

- We would like to thank Early Clinical Development Biometrics, ECD and AZ-ICDE team at AstraZeneca.
- We would also like to extend our thanks to ECD DM and A&R vendors, nnIT and Entimo AG.



Thank you!

Questions?

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