

Thinking Patient Centricity: Reflections on a Patient Centric Sampling (PCS) Case Study

Silvia Alonso Rodriguez

TSEM Operations Lead,

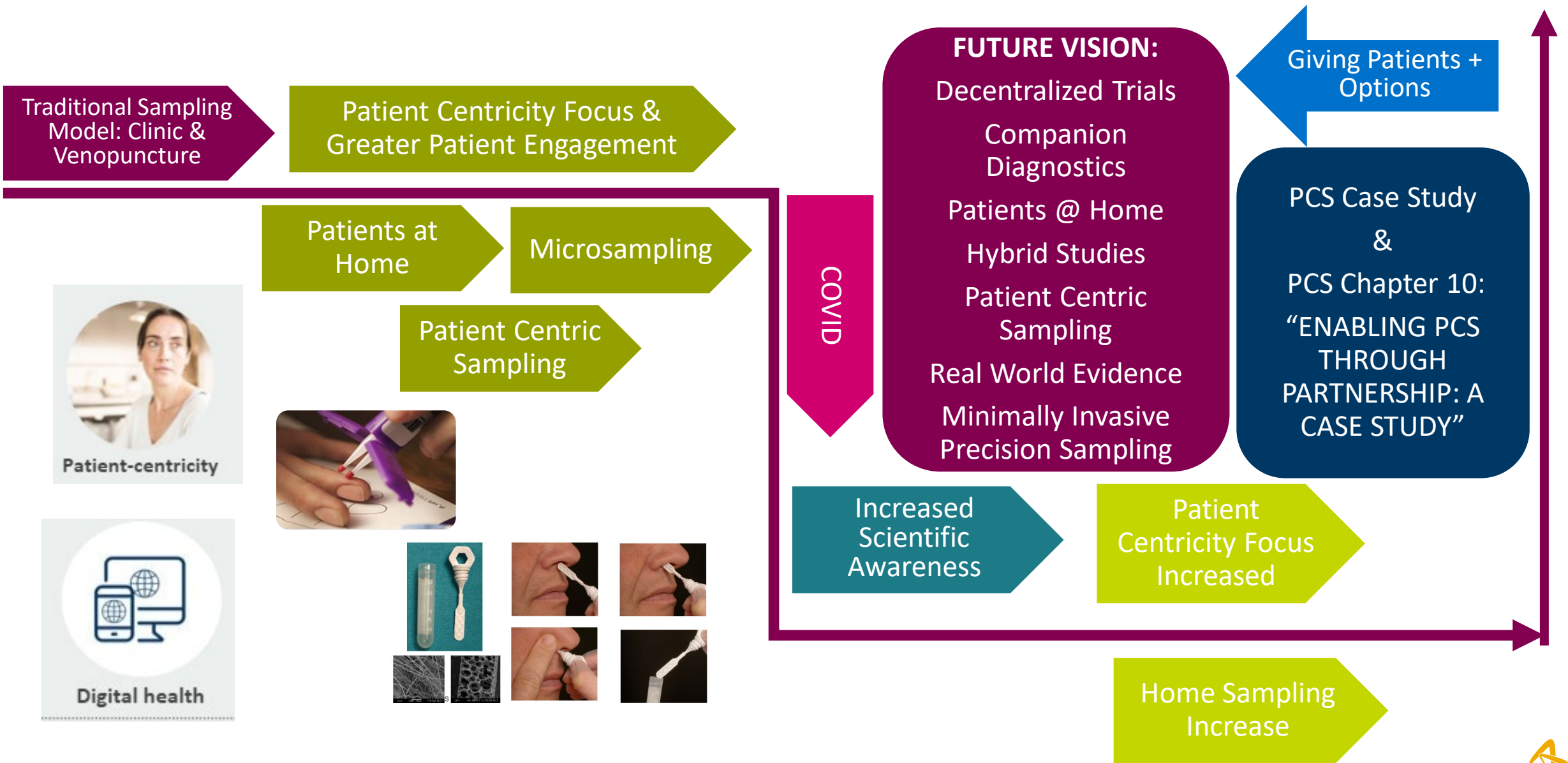
Translational Science & Experimental Medicine, eR&I

AstraZeneca

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1. Background- Patient Centricity Roadmap



2. What is PCS (Patient Centric Sampling)? AstraZeneca's PCS Approach

Traditional model based in venous blood procedures & patients at sites

Alternative sampling approaches aiming to reduce patients' burden, increase patients' on-study experience while preserving data quality & ensuring patients safety

Not aiming to replace venous & other sampling procedures but to complement them

Increase sampling flexibility for patients & patients' engagement

One size does not fit all: assessing feasibility & viability

AstraZeneca puts patients'safety first



3. Benefits-Why change to PCS?

- Less sample volume collected & most assays requiring low volume
- Improve patients on-study experience
- Potential faster enrolment and recruitment and higher patient retention
- Beneficial to a wider patient groups such as pediatrics
- Potential to increase patients' inclusion & diversity
- Give patients more opportunities for treatments
- New life changing treatments available sooner- **Improving Patients' Lives**



4. Why PCS isn't already the norm?

Balancing Feasibility & Benefit

Economic

- Initial increased costs
- Increased time
- Increased FTE

Operational

- Sampling handling
- Data Privacy
- Drug administration route

Scientific

- Data concordance
- Quality sampling procedures
- Validated assays for all matrices

Regulatory

- Bridging data comparison for all matrices & different settings (site & home)



5. PCS Case Study- Background

Phase I Adolescents Study

Hybrid model: Site & Home Visits

Nursing Company at Home

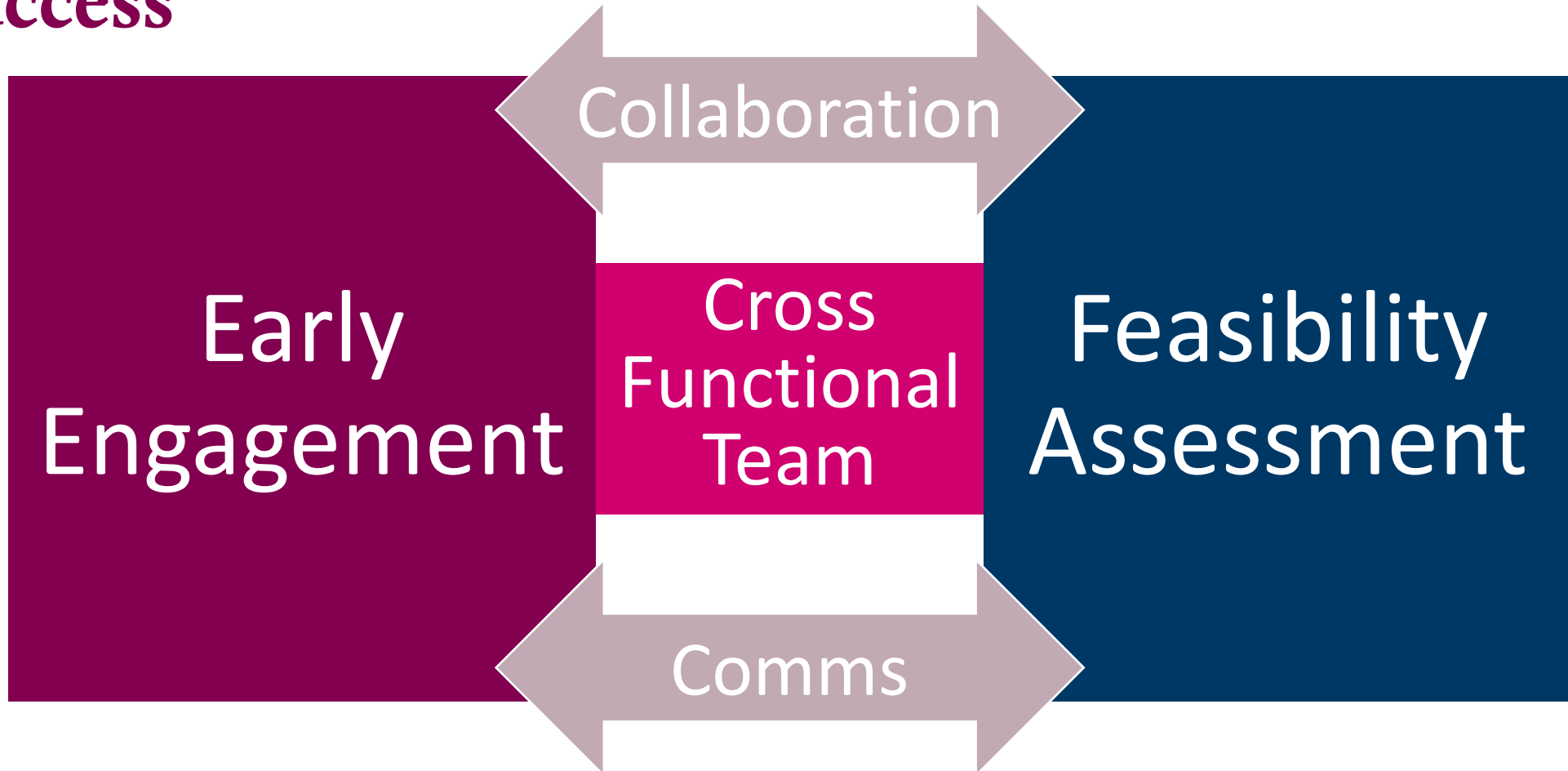
VAMS Micro Sampling & Venopuncture

Rationale-Impact on School for Patients

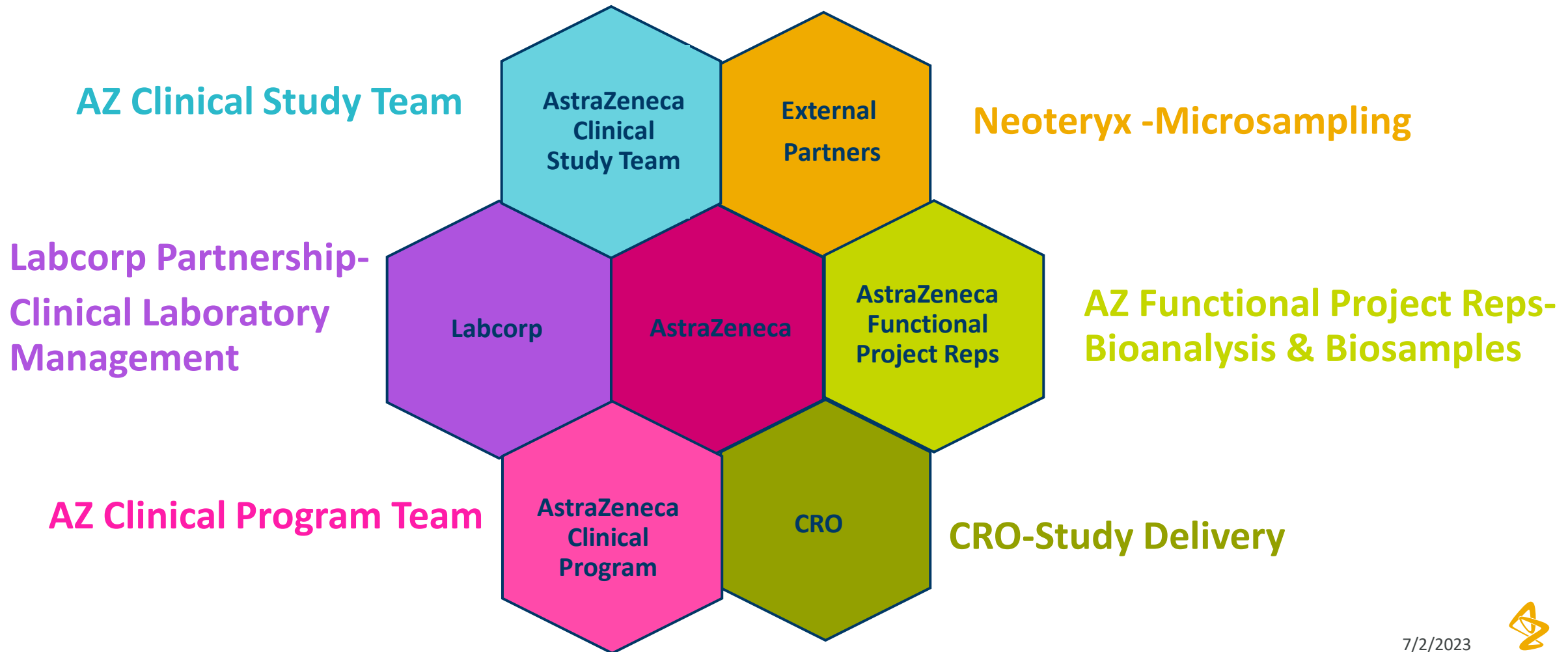
Labcorp Partnership



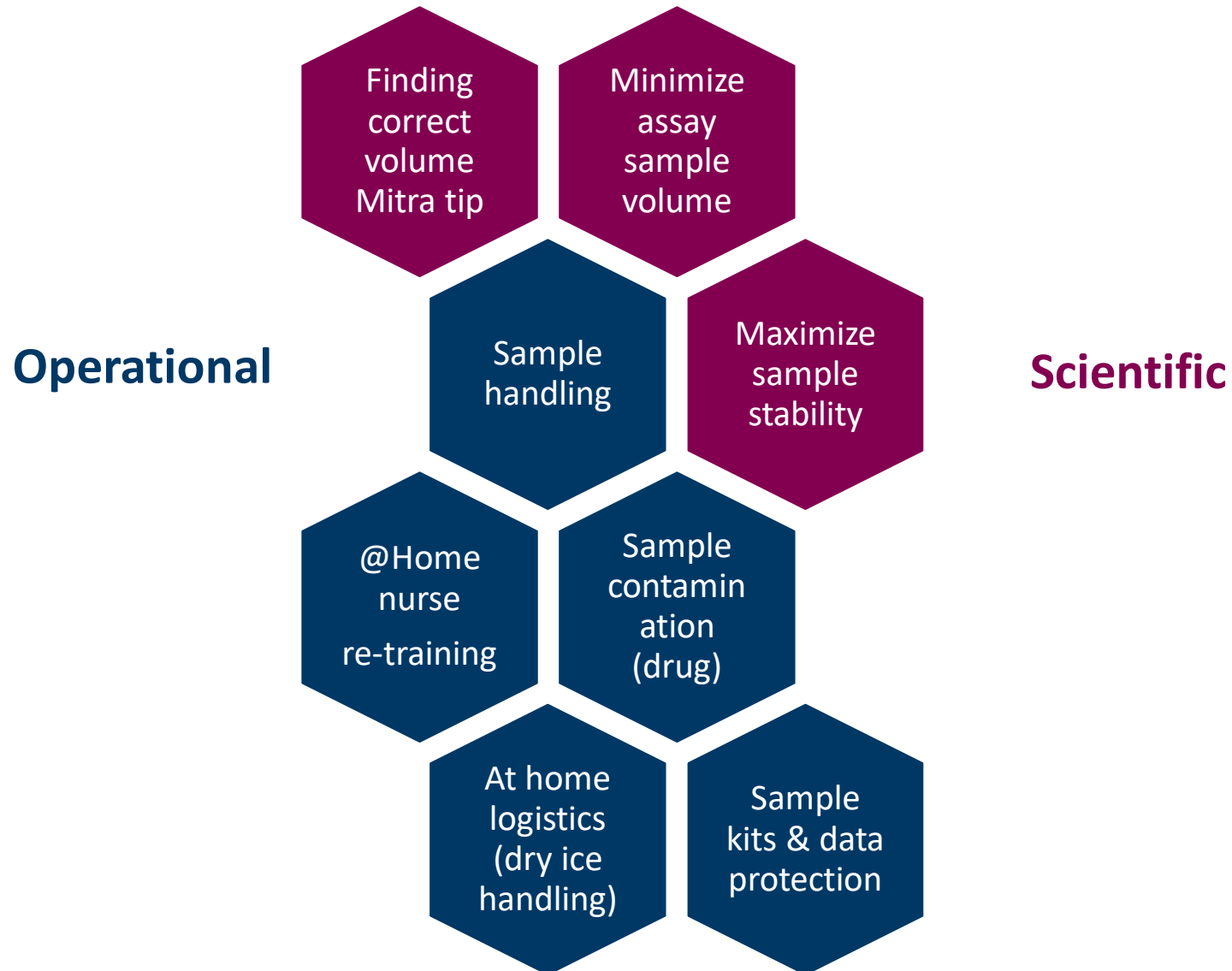
6. PCS Pre-study Key Considerations-Planning for Success



7. PCS Case Study- Stakeholder Map & Cross Functional Team



8. PCS Case Study-Complexity & Challenges



9. PCS Study-Defining Success



Early Engagement



Feasibility Assessment

Operational

Scientific

Economic

Regulatory



Cross Functional Work



Aligned Comms



thank
thank
you!



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