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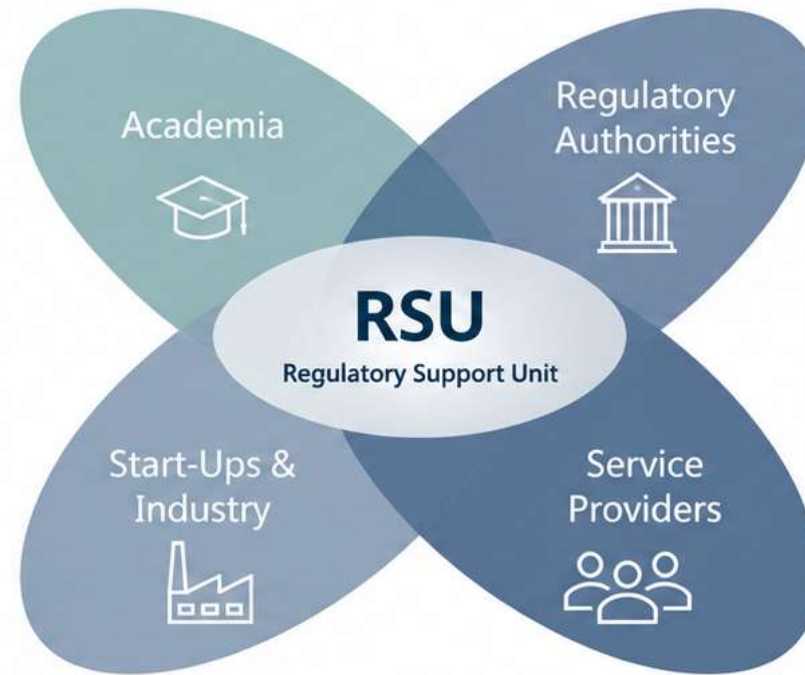
SaxoCell Conference 2026

**Regulation as a Compass -
Learnings from Two Years of Supporting Academic Translation**

The Regulatory Support Unit (RSU)

Who we are and how we started

- ❖ Easily accessible first contact point for regulatory support in Germany
- ❖ Independent and confidential, free of charge for academic teams
- ❖ Established as part of the National Strategy for Gene & Cell Therapies (GCT) in June 2024
- ❖ Regulatory Affairs specialists with a wide range of experience



RSU impact so far

Early support with national reach



>40

projects



11

Scientific Advice
meetings

plus additional interactions in preparation



*The RSU team was an
invaluable resource for my team*



Broad product diversity



Cell therapies



Gene therapies



ATMP-related platforms



Biologicals



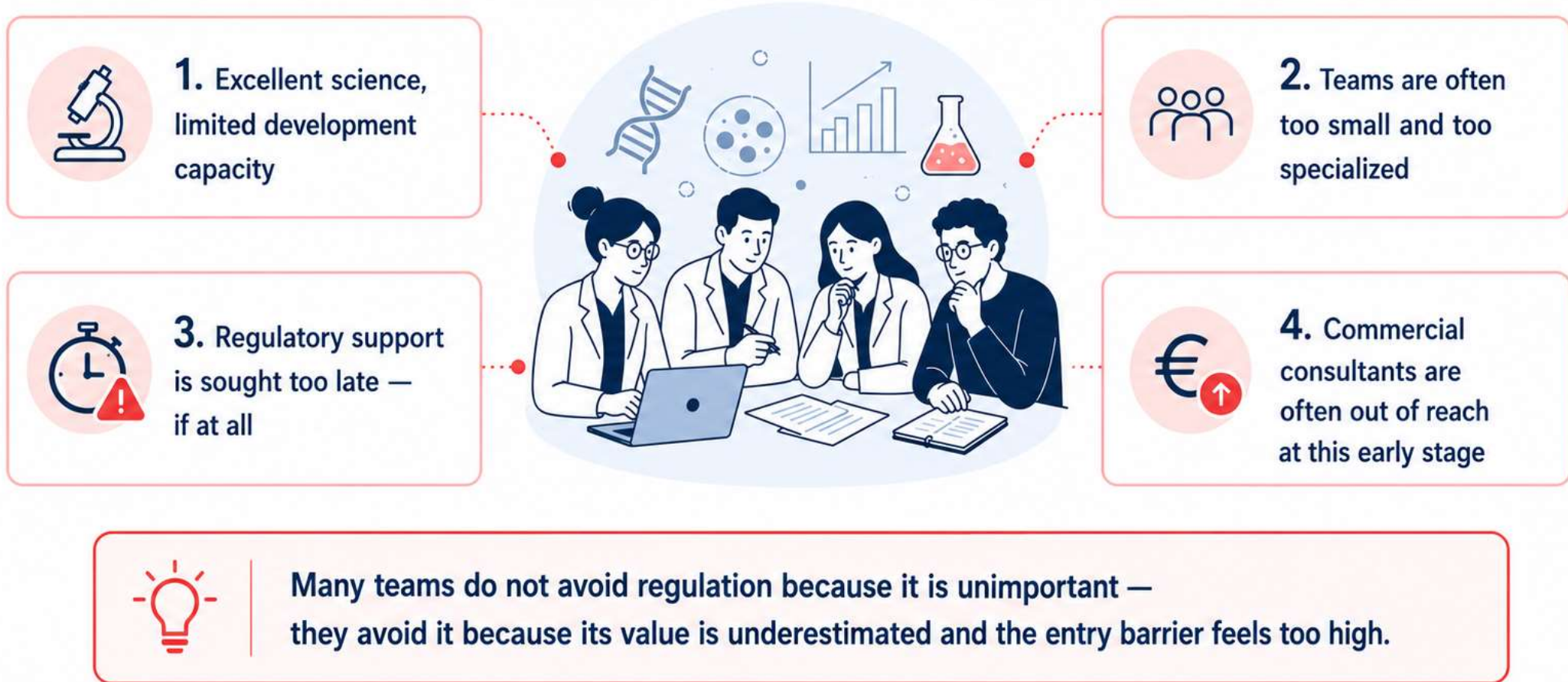
Translational projects



Accelerated development — increased chance of clinical translation

The academic translation gap

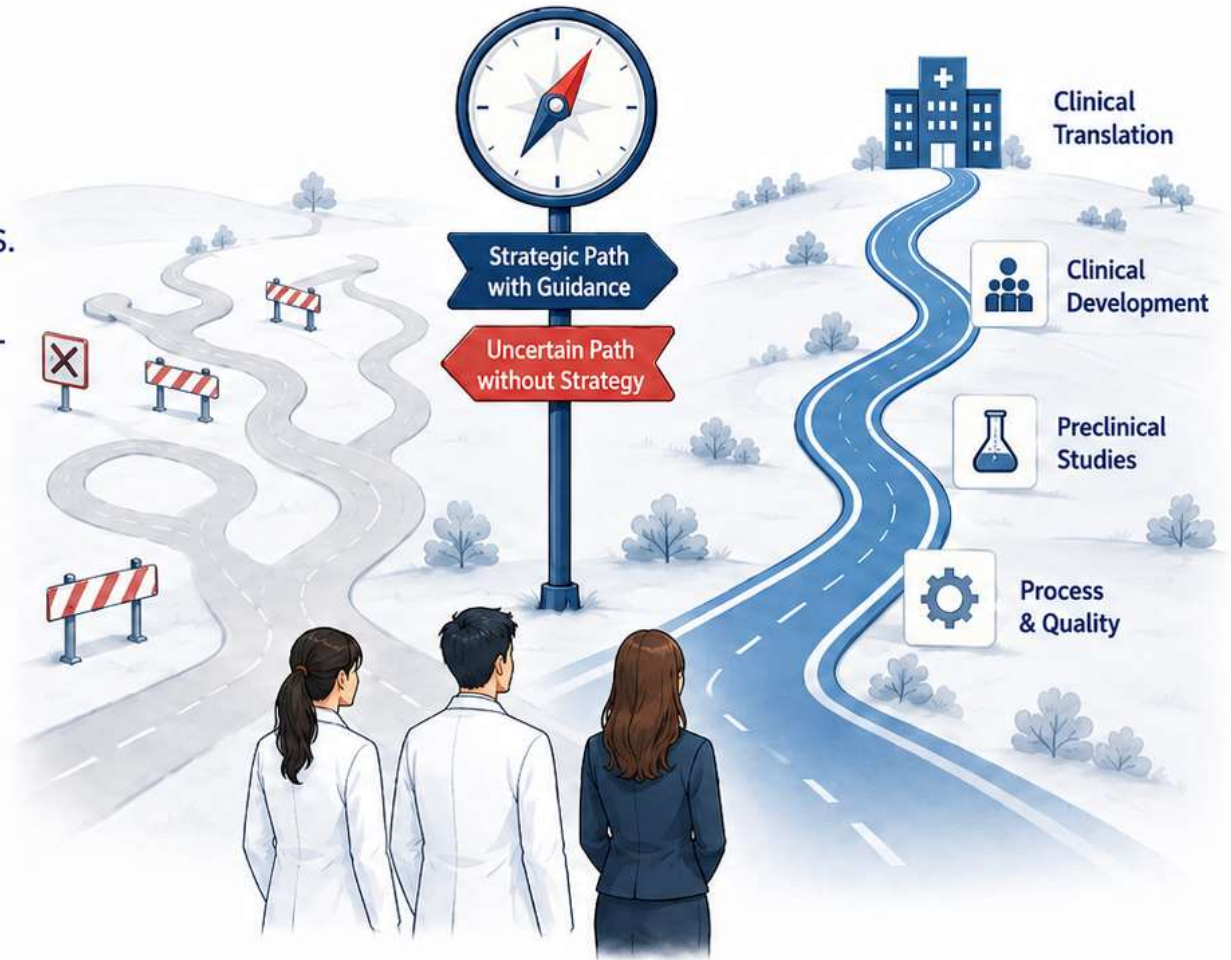
Why promising science often struggles on the path to development



Why early regulatory support matters

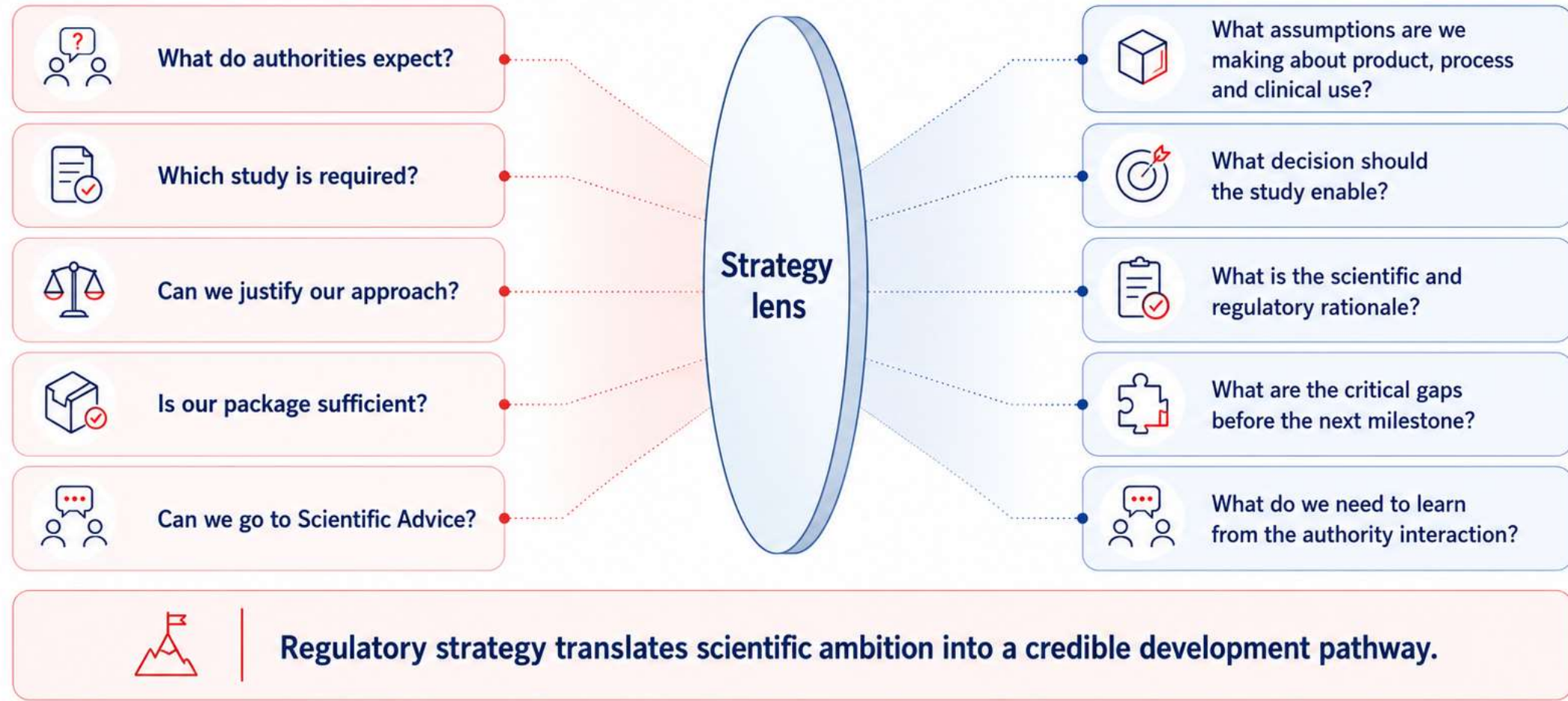
Regulation is a compass — not a hurdle at the end

- ❖ Without a regulatory strategy, development becomes a series of detours, delays and dead ends.
- ❖ For biologicals, the entire development pathway — product, process, quality, preclinical and clinical planning — is interconnected.
- ❖ Early guidance helps academic teams ask the right questions before critical resources are spent.
- ❖ Regulatory thinking can accelerate translation by reducing avoidable rework and risk.



From regulatory questions to development strategy

A single question often reveals a broader development issue



What the RSU is — and is not

A bridge for early regulatory guidance

What we are

- ✓ Independent
- ✓ Confidential
- ✓ Free of charge
- ✓ First contact point for academic teams in Germany
- ✓ Early guidance on regulatory strategy and development planning
- ✓ Support in preparing for interactions with authorities

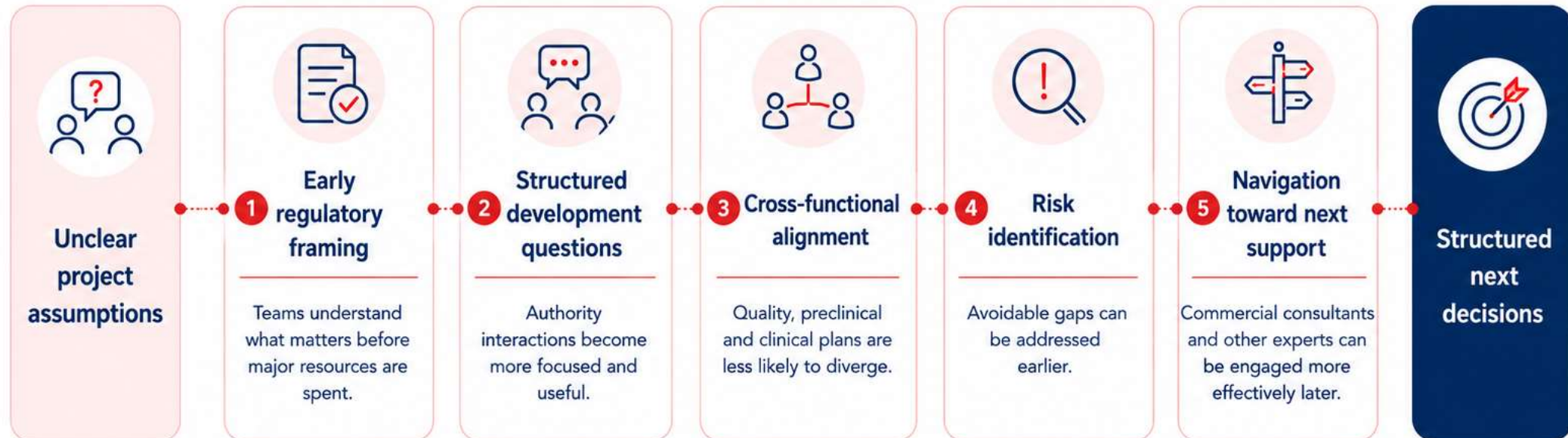
What we are not

- ✗ Formal legal advice
- ✗ Replacement for regulatory authorities
- ✗ Full-service regulatory consultancy
- ✗ Guaranteed approval pathway



How RSU creates value

By clarifying questions and helping structure early development decisions



The bridge function creates value by clarifying questions, shaping strategy and supporting well-structured next steps.

Key lessons

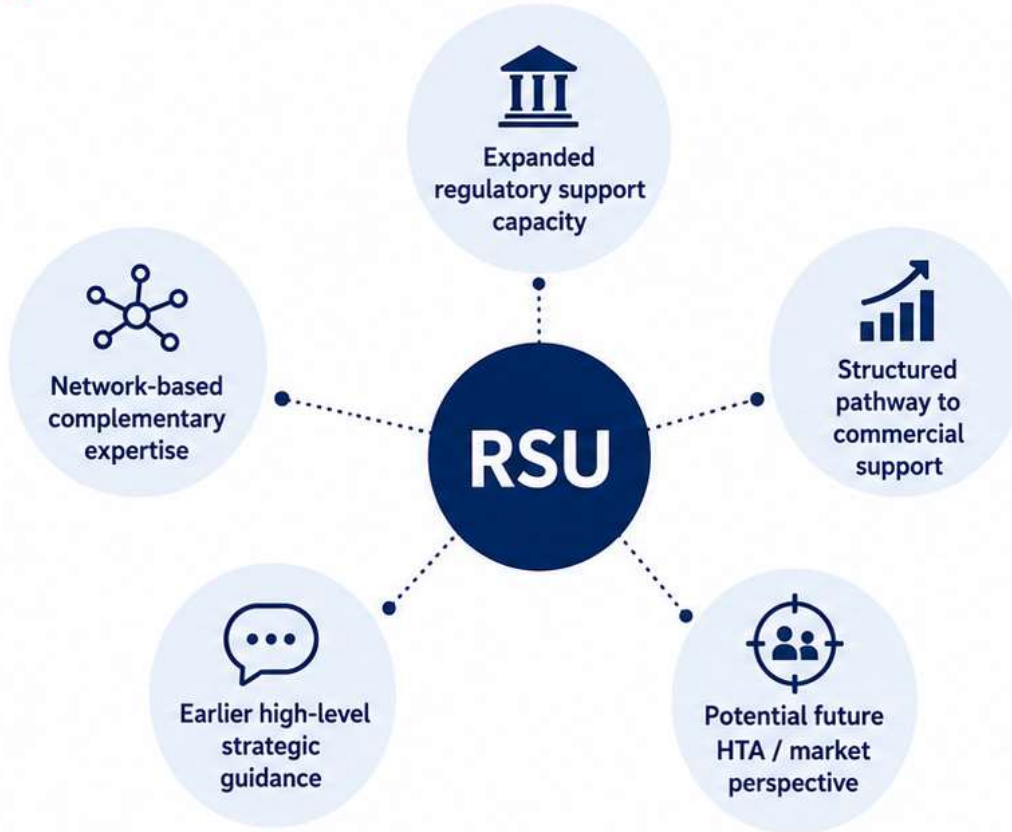
What repeatedly matters most



The recurring challenge is not about scientific quality — **it is about integrated development planning.**

Next step: Innovation Service Network

Building on the RSU model



Planned direction



Explore partner acceptance and collaboration



Strengthen support across the development pathway



Preserve early, accessible high-level guidance



The goal is not to replace existing actors, but to connect them earlier and more effectively.

Take-home messages

- 1** | Think about regulation early.
- 2** | For biologicals (especially GCT), development only works when quality, preclinical and clinical thinking are aligned.
- 3** | Academic teams need accessible first-contact support before they are ready for full consultancy structures.
- 4** | Regulation is not a hurdle — it is a compass for translation.

? Questions?

Thank you

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www.bihealth.org/en/translation/rsu

