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REGULATORY ROADMAPS TO TRANSLATE ACADEMIC ATMP INNOVATIONS INTO CLINIC

CHALLENGES FOR ACADEMIC ATMP

- Regulatory Knowledge Gaps
  Academic developers often lack understanding of ATMP regulatory frameworks.

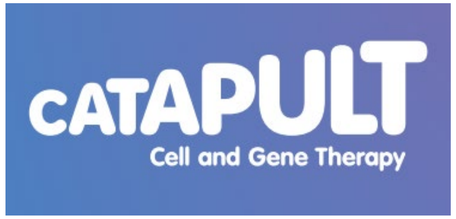
- Safety Considerations
  Unique ATMP safety issues, like immunogenicity and tumorigenicity, often require *more thorough early-stage evaluation*.

- Manufacturing
  Transitioning from research-grade to clinical-grade manufacturing is *complex and costly*.

- Infrastructure Limitations
  Academic environments frequently lack the infrastructure needed for smooth *translation to clinical trials*.

GAP IN REGULATORY UNDERSTANDING

- *Regulatory literacy* – important for the translation of innovation into commercial product.
- *Early regulatory engagement* is widely undervalued or misunderstood by academic founders.
- Need for *more accessible, harmonized regulatory guidance and resources* across Europe.



VALUE OF A REGULATORY ROADMAP

- Resource and Timeline Clarity.
  The roadmap aligns scientific innovation with regulatory expectations, clarifies decision points, timelines, and data needs, supporting realistic resource planning.

- Proactive Problem Identification.
  A well-defined roadmap enables early identification of scalability and compliance challenges to avoid clinical delays.

- Risk & Cost Reduction.
  Early coordination of CMC, non-clinical, and clinical planning reduces development risks and prevents costly rework.

IMPACT OF EARLY REGULATORY INTEGRATION

- Strengthening Evidence Packages.
  Proactive regulatory engagement ensures data is relevant, robust, and meets regulatory standards.
- Enhancing Credibility.
  Regulatory readiness signals project maturity, boosting confidence among funders, investors, and industry partners.
- Reducing Uncertainty and Risks.
  Early integration clarifies development pathways and regulatory risks, enabling efficient decision-making and timeline management.
- Accelerating Clinical Advancement.
  Unified regulatory and scientific strategy reduces delays, promoting faster transition from research to clinical testing.

KEY REGULATORY MILESTONES

- ATMP Classification.
  Obtaining classification from regulatory committees confirms product status and development requirements.

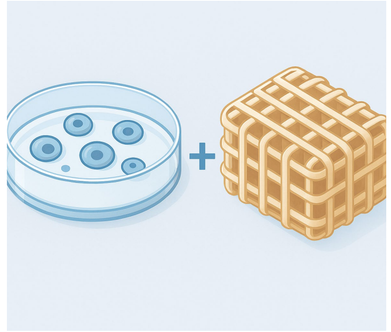
- Innovation Task Force Meeting.
  Early discussions with innovation task forces help identify concerns and offer informal guidance preclinically.

- Formal Scientific Advice.
  Formal advice from EMA helps address evidence gaps, validate development strategies, and gain feedback on CMC, non-clinical, and clinical plans.

CASE STUDY

Background:

European start-up, developing a combined ATMP (cell-seeded scaffold implant), lacked regulatory and CMC expertise for FIH readiness.



Challenges:

- Unclear ATMP classification due to device-cell integration.
- Non-GMP manufacturing and undefined CQAs.
- Insufficient non-clinical design addressing biodistribution, immunogenicity, and device interactions with cells/tissue.
- Fragmented CMC, non-clinical, and device-related documentation.

Solutions:

- ATMP classification request and device regulatory mapping.
- GMP gap analysis and redesign of manufacturing workflows.
- Non-clinical development plan aligned with intended clinical use.
- FIH regulatory strategy and ITF meeting preparation.

Outcome:

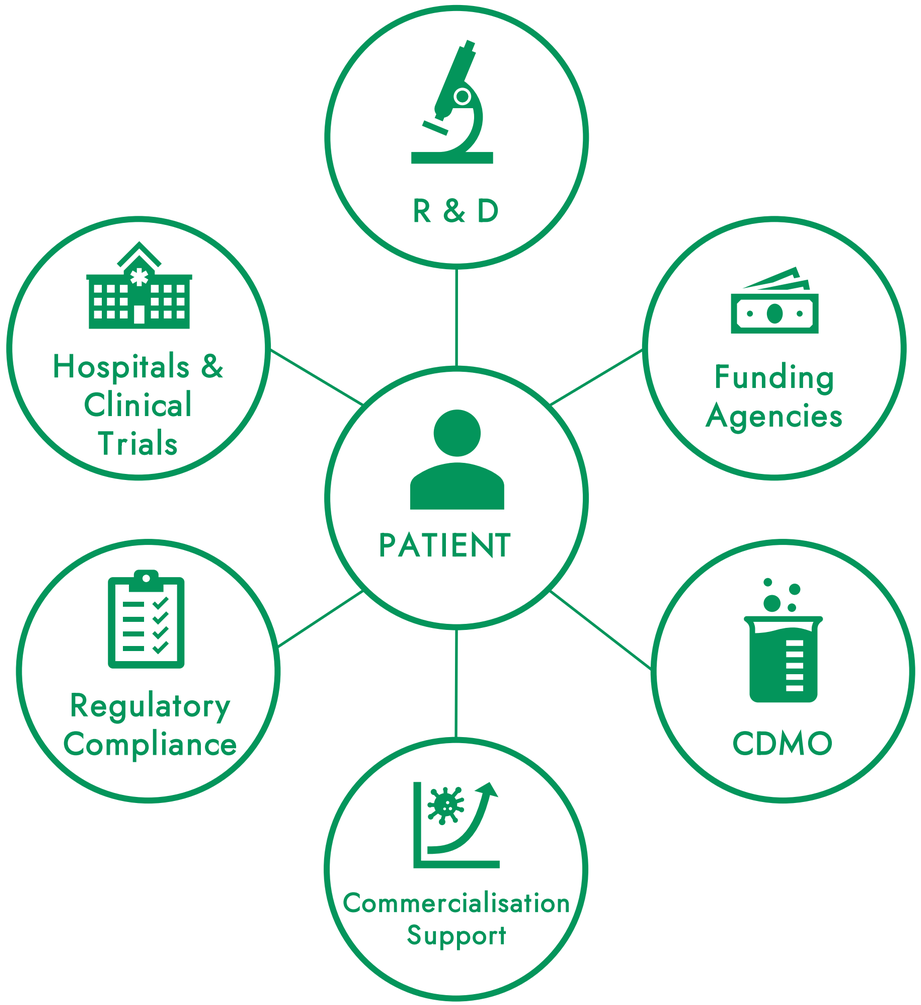
Successful alignment of regulatory strategy, enabling predictable progress toward FIH readiness and increased investor confidence.

KEY TAKEAWAYS

I. Reach out for help. Do not be afraid to ask questions to be able to generate the right data at the right time.

II. Early on proactive engagement with regulatory authorities.

III. Strengthen CMC (quality & safety) and manufacturing documentation for a compliant, scalable and "regulator-ready" transition from research-grade to clinical-grade product.



THANK YOU.

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