BUSINESS CASE

Case Study: From Bench to FIH (First-in-Human) — Supporting an ATMP Client

CHALLENGE

A client approached with a promising **ATMP product** facing significant barriers:

- Limited understanding of the complex **ATMP regulatory pathway**.
- Difficulty navigating essential **regulatory steps** from early development to clinical trials.
- Inexperience preparing a **Scientific Advice (SA)** meeting with the EMA or National Competent Authorities to validate quality, preclinical data and potential clinical design ahead of FIH studies.
- Uncertainty in aligning with regulatory agencies on critical milestones such as **clinical trial application (CTA)** and **Orphan Drug Designation (ODD).**
- Challenges preparing documents and activities such as **ATMP Classification, Investigational Medicinal Product Dossier (IMPD), Investigator's Brochure (IB), GMOs, ATMP certification, CTA.**
- Limited understanding of timelines, documentation, and stakeholder engagement for regulatory and project success.

SOLUTION

Regulatory Roadmap Preparation

- Developed a **tailored ATMP regulatory roadmap** from concept to clinical trial authorization, explaining mandatory steps as per EMA ATMP guidelines and legislation.

Strategic Regulatory Support

- Successfully prepared an **ODD application** to secure regulatory incentives.
- Facilitated and led **SA meetings** with authorities to address key regulatory and development questions.
- Prepared **ATMP certification, IMPD, IB, GMO application, and CTA** ensuring compliance with EMA standards for FIH trials and ATMP certification.

End-to-End Project Management

- Ensured efficient regulatory interactions and milestones with continuous scientific, regulatory, and medical writing support tailored to ATMP-specific challenges.

OUTCOME

Regulatory Clarity and Confidence

- Enabled the client to clearly and effectively navigate the ATMP regulatory environment with a clear and actionable plan.

Achievement of Key Milestones

- Facilitated positive SA outcomes, de-risking clinical development.
- Prepared and positioned the client's regulatory activities and documentation for smooth clinical trial authorization.

Accelerated Development Pathway

- Reduced delays and risks through proactive regulatory planning and comprehensive IMPD preparation.
- Established a solid foundation to support further clinical phases and eventual marketing approvals.

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