Target Product Profile (TPP)

Bridging Discovery to Clinical: A Roadmap for Market Success

Serum Life Science Europe GmbH

11.09.2025

SLS Europe Today - Core Competencies & Experience

Regulatory Consulting

- Clinical Trial Information System (**CTIS**) and submissions
- **Scientific advice** meetings in Europe, US, and globally
- Investigational new drug (**IND**) submissions
- Preparations of **clinical trial application** packages
- Pediatric investigational plans (**PIP**)
- ATMP classifications

Marketing Authorisation

- **Marketing Authorisation Application** globally
- **Marketing Authorisation Holder** (Sponsor) in Europe
- **Import** and **Release**
- In house **Pharmacovigilance** System

GCP Services & Sponsorship

- Full **sponsor** responsibility
- **Representative of the sponsor** in EU
- Clinical project management
- Quality oversight

Translational Project Management

- **Reverse-planning** approach for product development
- Preparation of Target Product Profile (**TPP**)
- Validation
- Budgeting
- **Risk analysis** (including gap analysis, red flag analysis)

Quality Assurance Implementation

- **QMS** consultancy
- **GCP & QA training**
- Support in ensuring **compliance with GxP**
- GCP audit & inspection readiness

Medical Expertise

- Conduct of >70 clinical trials

Thereof: 12 with monoclonal antibodies,
38 small molecules,
7 vaccines,
6 biologicals,
2 medical devices

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Target Product Profile (R&D Perspective)

T.P.P. as a planning tool in drug discovery research.

The process of developing the T.P.P. is seen as an excellent way to identify and develop working relationships with all stakeholders in the project.

- Strategic perspective
- Medical and commercial requirements
- Patient requirements
- Technical features
- Technical requirements
- Technical feasibility
- **Desired versus minimally acceptable features**

Regulatory Strategy

Early and clear definition of the indication and target population is crucial for regulatory submissions and approvals.

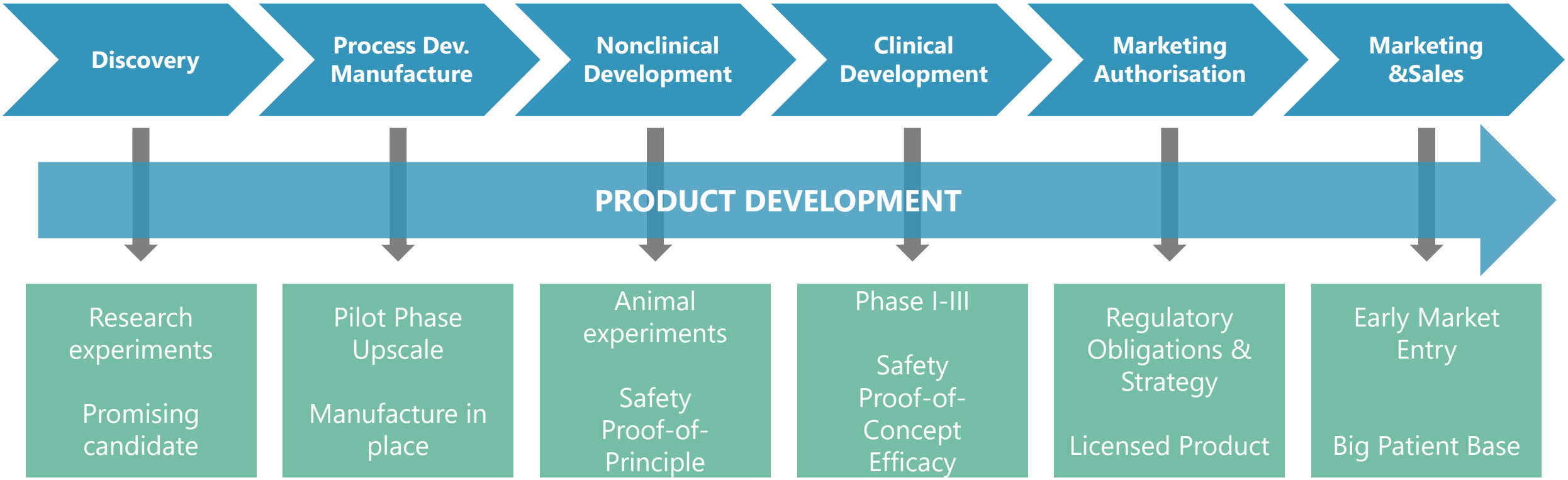
Engaging with regulatory agencies to get feedback on the chosen indication and population to ensure alignment with regulatory expectations.

Expedited programs: Selecting an indication that qualifies for orphan drug designation or other expedited review programs can speed up development and approval.

Regulatory Strategy Plan

- Preparation of a Target Product Profile (Indication and target population)
- Regulatory Landscape Assessment
- Preclinical and Clinical Development Strategy
- Quality and Manufacturing Strategy
- Early Engagement with Regulatory Agencies
- Timelines for Regulatory Submissions and Interactions
- Global Harmonization and International Requirements
- Risk Management

Traditional R&D Planning …but…



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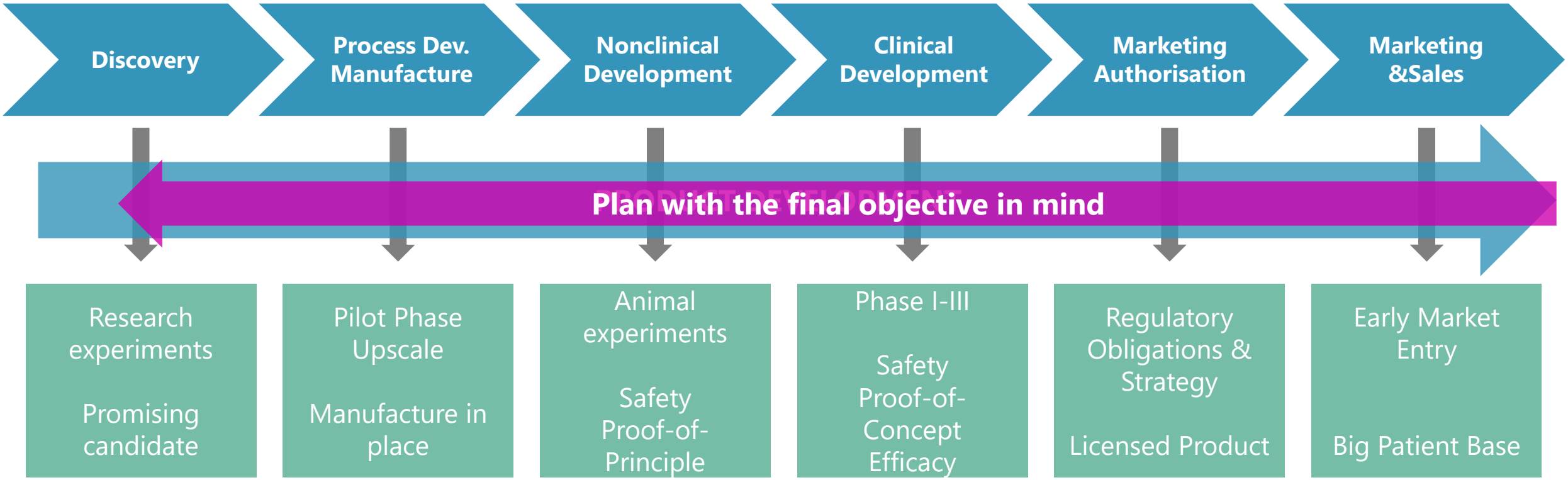
The **SLS** Way: in a **Reverse Approach**



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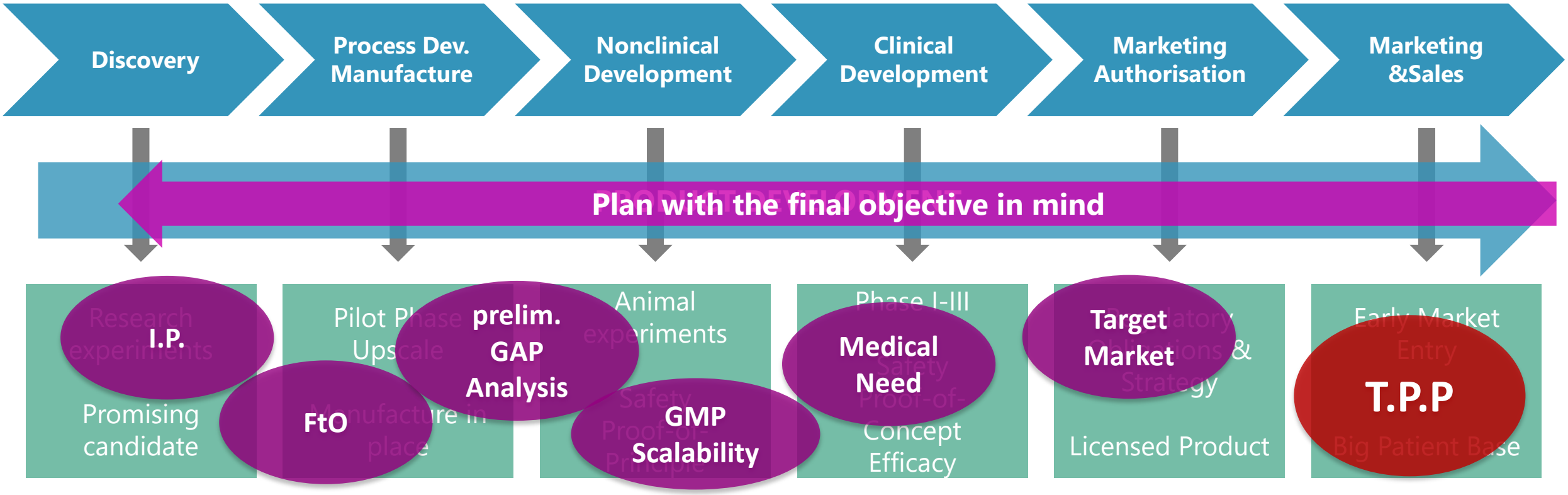
… with **Deliverables**, **Market** and **Exit** in Mind



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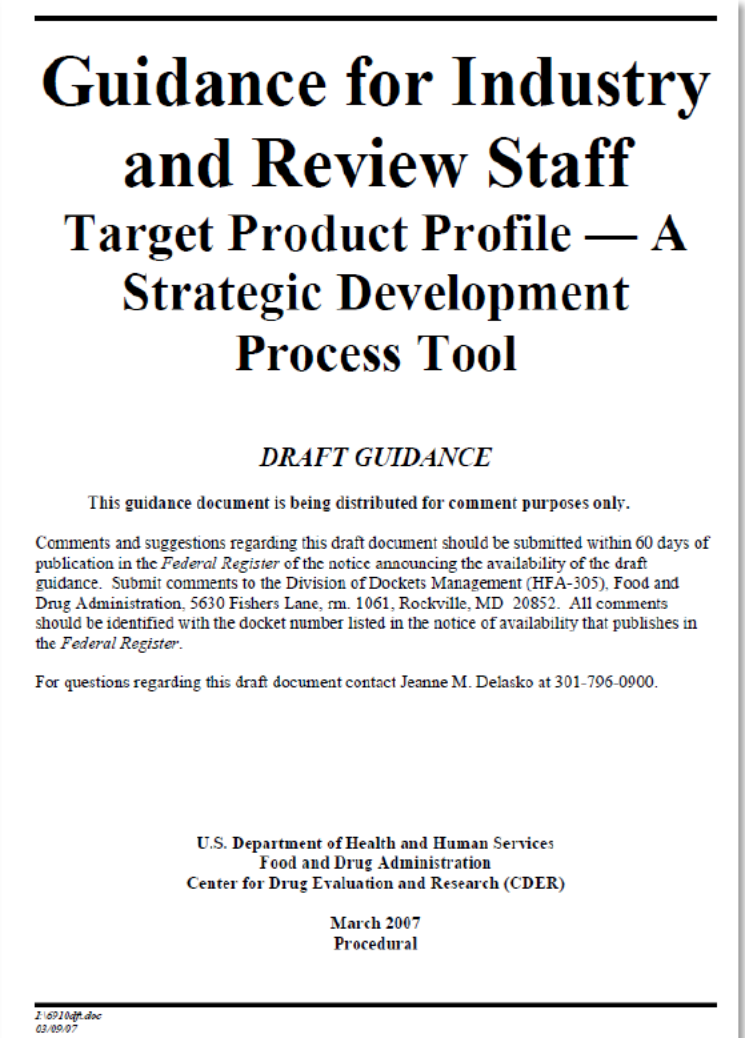
Target Product Profile (Industry Perspective)

Key Elements

Product
Target indication and patient segment
Target population
Key geographical markets
Key efficacy claim
Safety
Dosage / volume / route
Onset and duration of effect
Stability, shelf life
Presentation, formulation
Price US / EU / ROW
Gold standard for targeted disease
Launch date



Guidance for Industry and Review Staff

Target Product Profile — A Strategic Development Process Tool

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Jeanne M. Delasko at 301-796-0900.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2007
Procedural

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The T.P.P. (Industry Perspective)
An organised "wish-list" of features

Key claims at launch	Base case
Product	VAC-X, alum-adsorbed recombinant protein vaccine against *Bug pathogenus* generating a humoral immune response against the ProT protein, one of the main *Bug pathogenus'* virulence factors
Target Indication and Patient Segments	Active immunization against *Disease* caused by *Bug pathogenus'* (and possibly other *Bug* species) in at risk subjects (base case)
Target Population	Subjects with recurrent episodes of *Bug pathogenus* infections
Key Geographical Markets	Seven Major Markets (USA, Germany, France, Great Britain, Spain, Italy, Japan)
Key Efficacy Claim	At least 60% reduction in number and/or severity of recurrences caused by *Bug pathogenus* for 24 months after completion of vaccination course (possibly maintained by a booster)
Safety	Profile similar to HBV recombinant licensed vaccines. Better tolerability than current treatment (liver toxicity of chemotherapic compounds)
Dosage/volume/route	50mcg/0.5 mL/IM 3 administrations within 6 months, 1 month apart + potential booster at 12 months.
Onset and Duration of Effect	Onset 3-4 weeks after completion of full vaccination course with a protection duration of 12 months
Stability/Shelf life	At least 2 years at launch
Presentation/ Formulation	PFS/full liquid API: recombinant ProT Adjuvant: Aluminum phosphate Excipients: PBS pH 7.4 Solvents: WFI
Price- US/EU/ROW COGs	$250/course (US); COGs:~$15/dose
Gold standard for targeted disease	Current guidelines: suppressive regimen of oral chemotherapic X for at least 6 months (usually once weekly at a dose of 150 mg)
Launch Date	2023

The T.P.P. (Industry Perspective)
An organised “wish-list” of benefits

- The Unique Selling Proposition (USP)
- „Must have‘s“ to differentiate from competitors
- „Must have‘s“ to fit into company‘s franchise
- Company specific „brand“ characteristics (e.g. colour)

Selection of a Suitable Indication and Target Population

Dr. Leander Grode

Serum Life Science Europe GmbH

formerly VPM

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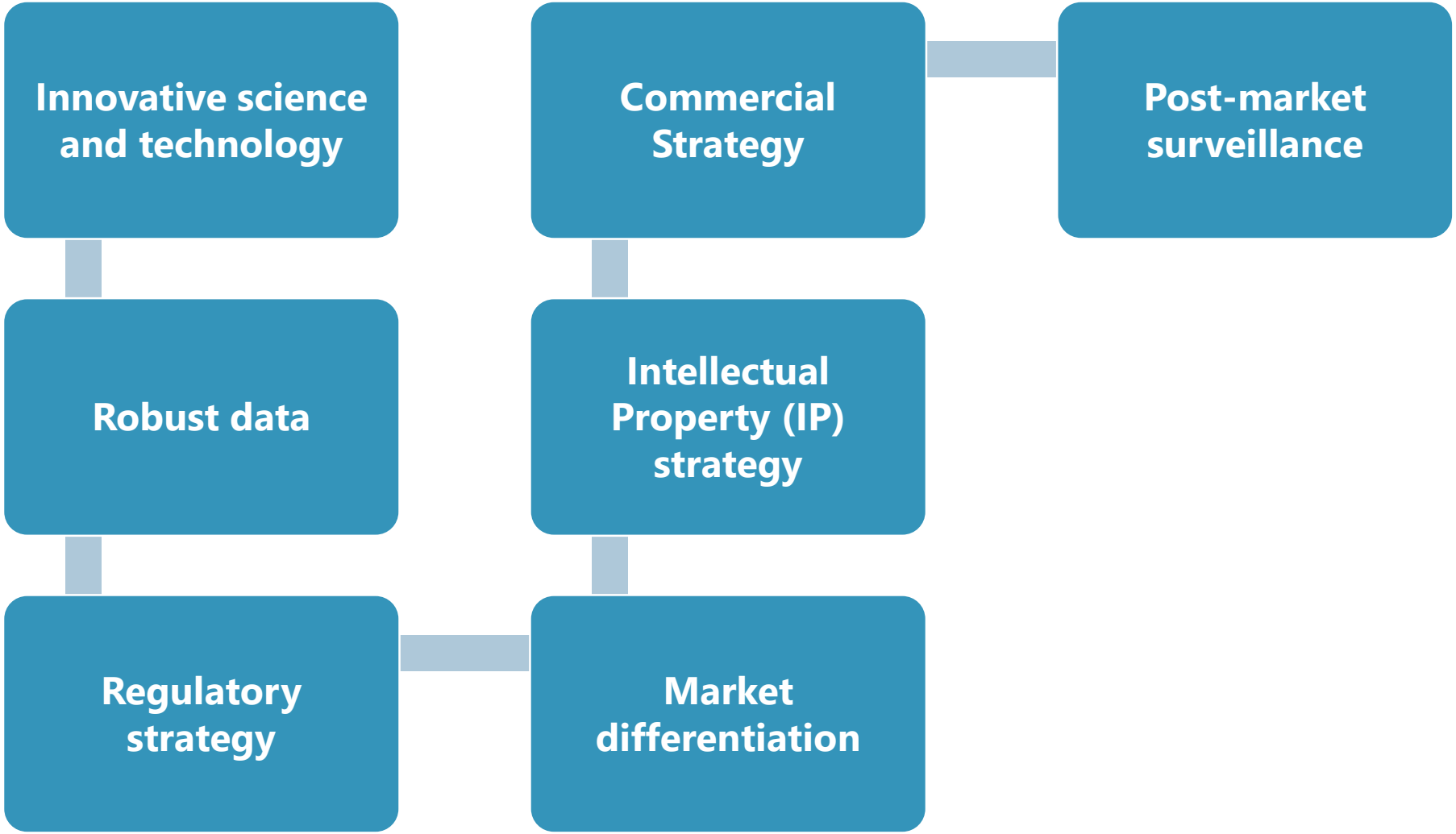
Making your product development unique and achieving commercial success



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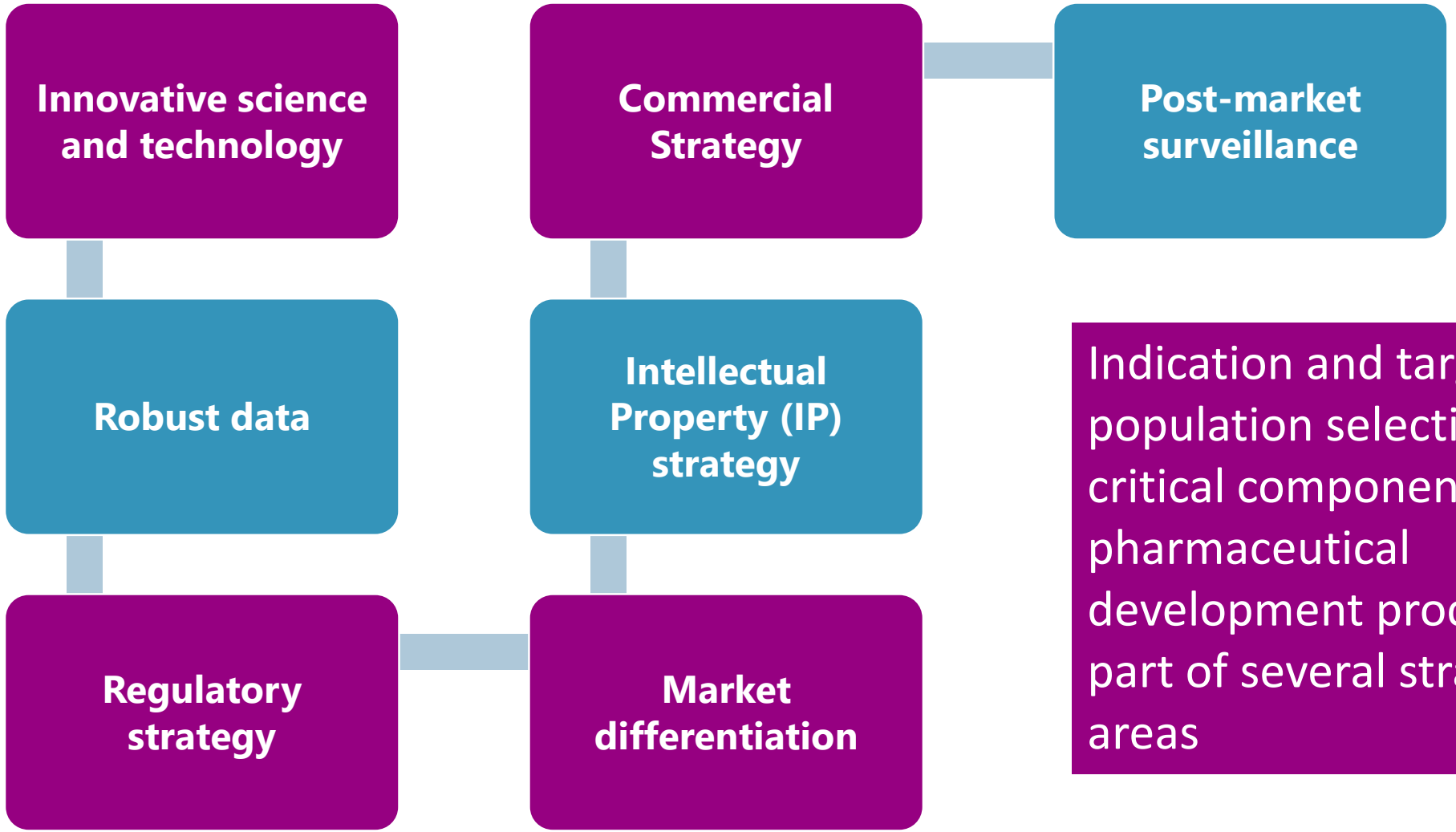
Making your product development unique and achieving commercial success



Indication and target population selection are critical components of the pharmaceutical development process and part of several strategic areas

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Indication and Target Population Selection Is An Integrated, Cross-Functional Process

Input from R&D, regulatory, commercial, and medical affairs teams.

Alignment with the pharmaceutical's scientific basis, regulatory pathways, and market opportunities.

A well-designed product development program:

- **Maximizes its clinical impact**
- **Streamline the regulatory process**
- **Enhance its commercial viability**

Challenges and Mitigation Strategies

Challenges:

- Heterogeneity of patient populations.
- Regulatory hurdles and evolving guidelines.
- Limited data in early development stages.

Mitigation Strategies:

- Robust preclinical studies.
- Early engagement with regulatory bodies.
- Adaptive and flexible trial designs.

Commercial Strategy

Impact the commercial strategy, including **market sizing, pricing, and reimbursement**.

Market Research: Understanding the size of the target population, their specific needs, and how to reach them.

Health Economics and Outcomes Research (HEOR): Demonstrating the value of the drug in the selected indication and target population through cost-effectiveness analyses and real-world evidence.

Understanding Indication and Target Population

Determines the focus of clinical trials.

Influences regulatory pathways and market potential.

FDA and EMA Guidelines:

- Understanding the regulatory requirements for indication and target population.

Adaptive Trial Designs:

- Flexibility in trial design to address varying patient responses.

Pediatric and Orphan Drug Designations:

- Special considerations for vulnerable populations and rare diseases.

Influences clinical trial design, regulatory approval, and market success.

Age groups, genetic profiles, disease severity, comorbidities.

We look forward to working with you!

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TWINCORE

TWINCORE & SLS EUROPE JOINT SYMPOSIUM 2025

ADVANCES IN TRANSLATIONAL INFECTION RESEARCH AND IMMUNOLOGY

18.-19. SEPTEMBER 2025

Speakers

- Mathias Heikenwälder (Uniklinik Tübingen / DKFZ)
- Mathew Palmer (Accelagen)
- Kathrin de la Rosa (CiiM / MHH)
- Jannik Prentø (University of Copenhagen)
- Joe Grove (University of Glasgow)
- Kerstin Ludwig (Universität Bonn)
- Jeffrey Brown (PETA)
- Zahra Raisi-Estabragh (Queen Mary University of London)
- Nina Hobi (Alveolix)
- Stefan Kaufmann (MPIIB)
- Berit Lange (HZI)
- Karsten Fischer (Umlaut.Bio)
- Thomas Pietschmann (TWINCORE)
- Yannic Bartsch (TWINCORE)
- Heike Gielen-Haertwig (IBT - BT Lower Saxony)
- Patrick Behrendt (TWINCORE)
- Bobby Reddy (Immunity Bio Inc.)
- Agustin Fernandez III (Rational Vaccines Inc.)
- Henning Jacobsen (HZI - Endurivac)
- Frank Pessler (TWINCORE)
- Sezai Taskin (ViferaXS)
- Christian Kannemeier (HTGF)
- Yannick Frommeyer (TWINCORE)
- Teunie Westera (Bilthoven Biologicals)
- Wolfgang Weiß (Weickmann & Weickmann)
- Umesh Shaligram (Serum Institute of India)

Panel Session

- Asisa Volz (University of Veterinary Medicine Hannover)
- Thomas Pietschmann (TWINCORE)
- Agustin Fernandez III (Rational Vaccines Inc)

Thank you very much for your attention!

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