

Developing a Target Product Profile for a Preventive HIV Vaccine



Global HIV Vaccine
Enterprise

Topics to be Covered

- Overview of TPPs
 - What are they?
 - What is the purpose and benefit of using a TPP?
 - What is usually in a TPP?
- What are the unique issues for a TPP for HIV vaccines?
 - Comparisons with other vaccines
- How can a TPP best be used to support HIV vaccine development?



TPP Background and History

- In 1997, a working group with FDA and industry members recommended developing a template to:
 - summarize drug labeling concepts
 - focus drug development process
 - facilitate discussions between FDA and product developers
- This led to the development of the **Target Product Profile**



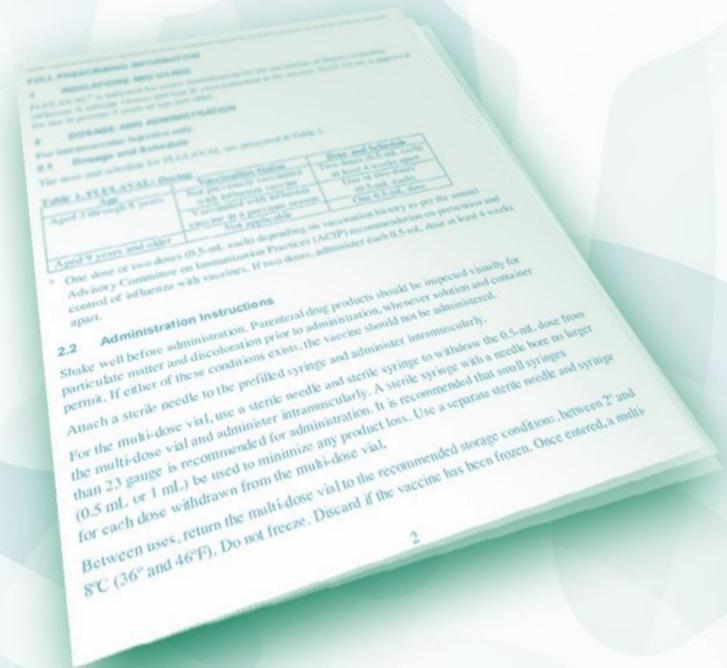
WHY?

From regulatory perspective, the product package insert (labeling) and the product claims **must** be supported by relevant studies and data.

In the past, companies would commonly request approval for indications or products that had not been included in the development plan.

Clinical data in men 18-30 years old may permit approval only for men 18-30 years old – not helpful if indication is primarily in men >50

Clinical studies demonstrating a reduction in pain may not support a labeling claim for reduction in associated disease symptoms – not helpful if pain reduction is considered insufficient for approval by regulatory agency



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FDA Guidance for Industry “Target Product Profile –
A Strategic Development Process Tool” (2007)

TPP emphasizes the concept of **beginning with the goal in mind**

The document should lay out the
desired labeling claims –
indication, target population,
product characteristics

These label claims should be
used to design the studies that
are needed to support the claims



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The TPP Today

- Original concept adopted and expanded beyond label claims
- Widely used by industry to assist and direct product development programs internally
- Emphasis remains on defining the goal in advance, and systematically working toward this goal
- Often includes criteria for “minimally acceptable target” and “desired target”
 - Different studies may be required to support minimal and desired targets
 - Frequently, the minimal target represents a shorter path to licensure, and post-licensure studies are conducted to incorporate additional targets

Attribute	Desired Target	Minimally Acceptable Product	Studies that support the target
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The TPP Today

The TPP has evolved into a strategic document that is widely used by product developers and has expanded to incorporate additional product attributes not covered by the labeling

- Marketing attributes
 - Competitive advantage relative to competitor products, cost to produce versus anticipated sale price
- Corporate attributes
 - Portfolio management, ROI
- Governmental/medical affairs
 - Potential for reimbursements
 - Assessment of product uptake by medical providers and public



Benefits of Using a TPP

- Delineates information needed for product success
- Aids product development team in specifying product characteristics to ensure appropriate studies
- Serves as a benchmark and tracks changes to the plan, and rationale for changes



Benefits of a TPP

Without a TPP – claims are broad and non-specific	With a TPP – claims are well-defined and quantifiable	
Label Claims		
“Vaccine against chickenpox”	80% efficacy in healthy adults >18 after 3 doses	Defines requirements for efficacy study
Storage conditions?	Stable at 2°C-8°C for 2 years	Defines formulation and stability requirements
Marketing Concepts		
Cost?	<\$2.00/dose	Defines requirements for manufacturing and packaging
Public Perception		
“Everyone will want this vaccine”	Requires 80% uptake for commercial success Requires recommendation by vaccine advisory groups	Defines needed market research studies

Note: The TPP defines the studies that are needed to achieve the desired product

An Example – Influenza Virus Vaccine

Attribute	Desired Target	Minimally Acceptable
Efficacy	Prevention of influenza disease caused by virus types contained in the vaccine Efficacy \geq licensed product	Demonstration of immune response to antigens in the vaccine that meet requirements of FDA Guidance (accelerated approval without clinical data)
Target population	Individuals >6 months old	Individuals >18 years old
Components	HA antigens from four influenza strains (quadrivalent) Preservative-free	HA antigens from three influenza strains Preserved with thimerosal
Product presentation	<ul style="list-style-type: none"> • 10-dose vial, preserved • Single-dose, no preservative • Intradermal • High Dose 	10-dose vial, preserved
Shelf life	One year (to cover one flu season)	6 weeks

Each of the targets represents a label claim that must be supported by the appropriate data set. Frequently, the minimal target represents a shorter path to licensure, and post-licensure studies are conducted to incorporate additional targets. The TPP should describe the specific studies that are required to meet both targets.

Attributes of a Vaccine TPP

Labelling Concepts	
Indications	Efficacy (Clinical studies)
Target population	Dosage schedule
Components (description)	Duration of protection
Product presentation	Safety and Tolerability
Route and method of administration	Co-administration
Shelf-life and storage	Clinical pharmacology
Additional Attributes	
WHO prequalification	
Registration pathway	
Target price	

Specific attributes to include in a TPP are product and project specific – a strategic decision by the project team

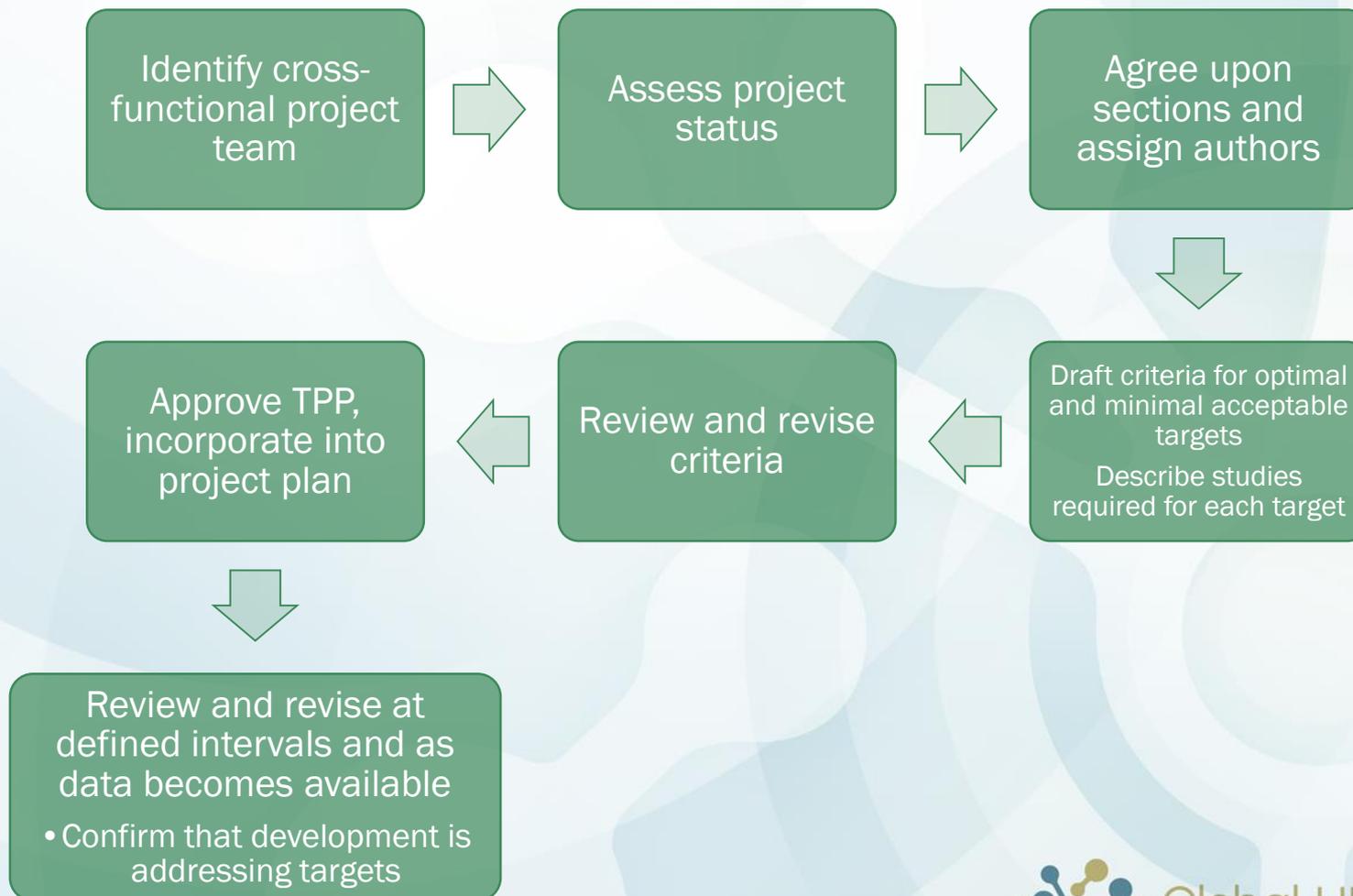


Developing a TPP

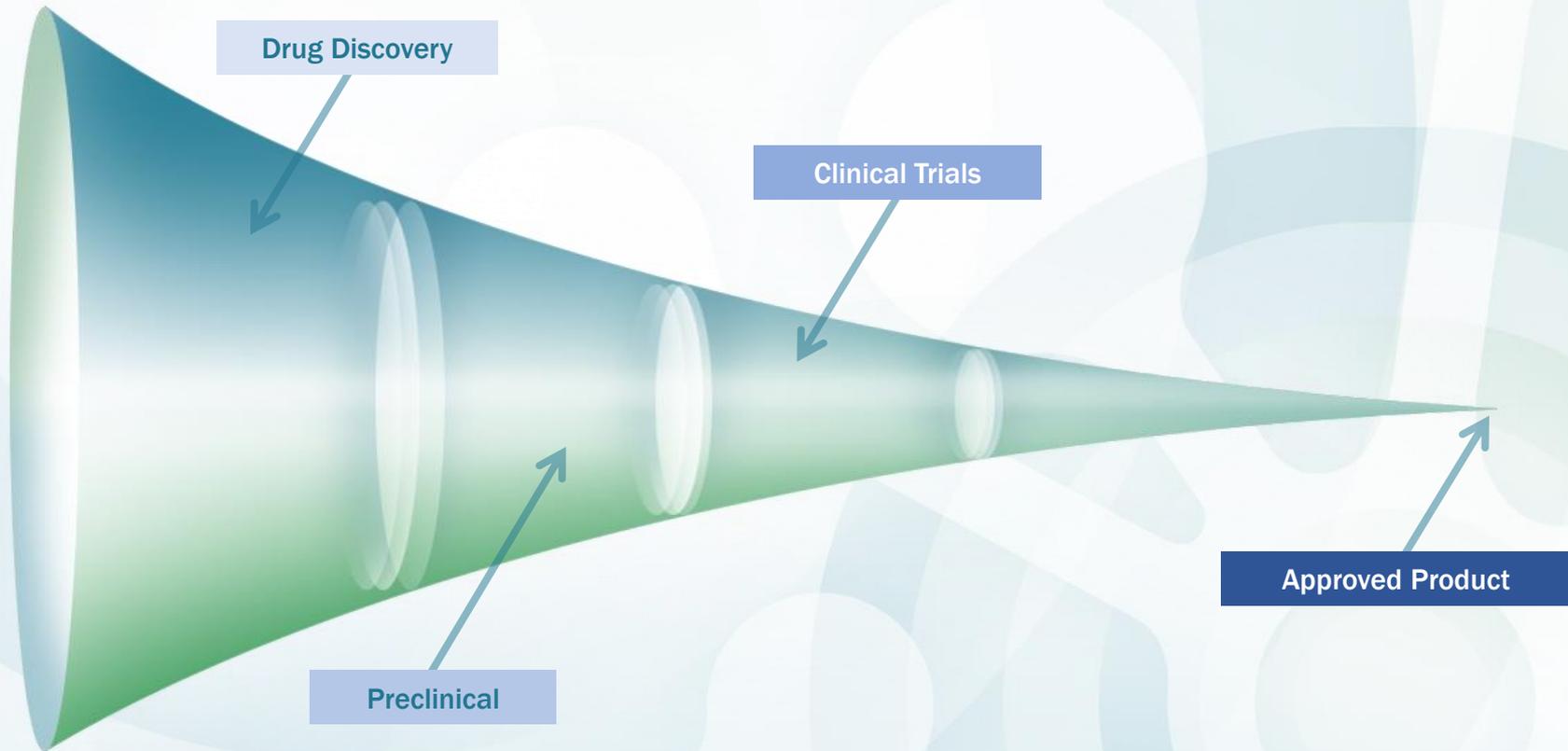
- Should be developed with input from all stakeholders
 - Regulatory, commercial, government affairs, clinical, intellectual property, external interested parties
- Identifies characteristics of a minimally acceptable product and the optimal product
- A living document: reviewed and updated periodically
- Specific attributes and the level of details depend on:
 - Nature of the product
 - Stage of product development



Preparing a TPP



When Should a TPP Be Developed?



- No specific time that a TPP is required
- Earlier TPP helps minimize the risk of irrelevant activities and increase the likelihood that meaningful preclinical and clinical studies are conducted



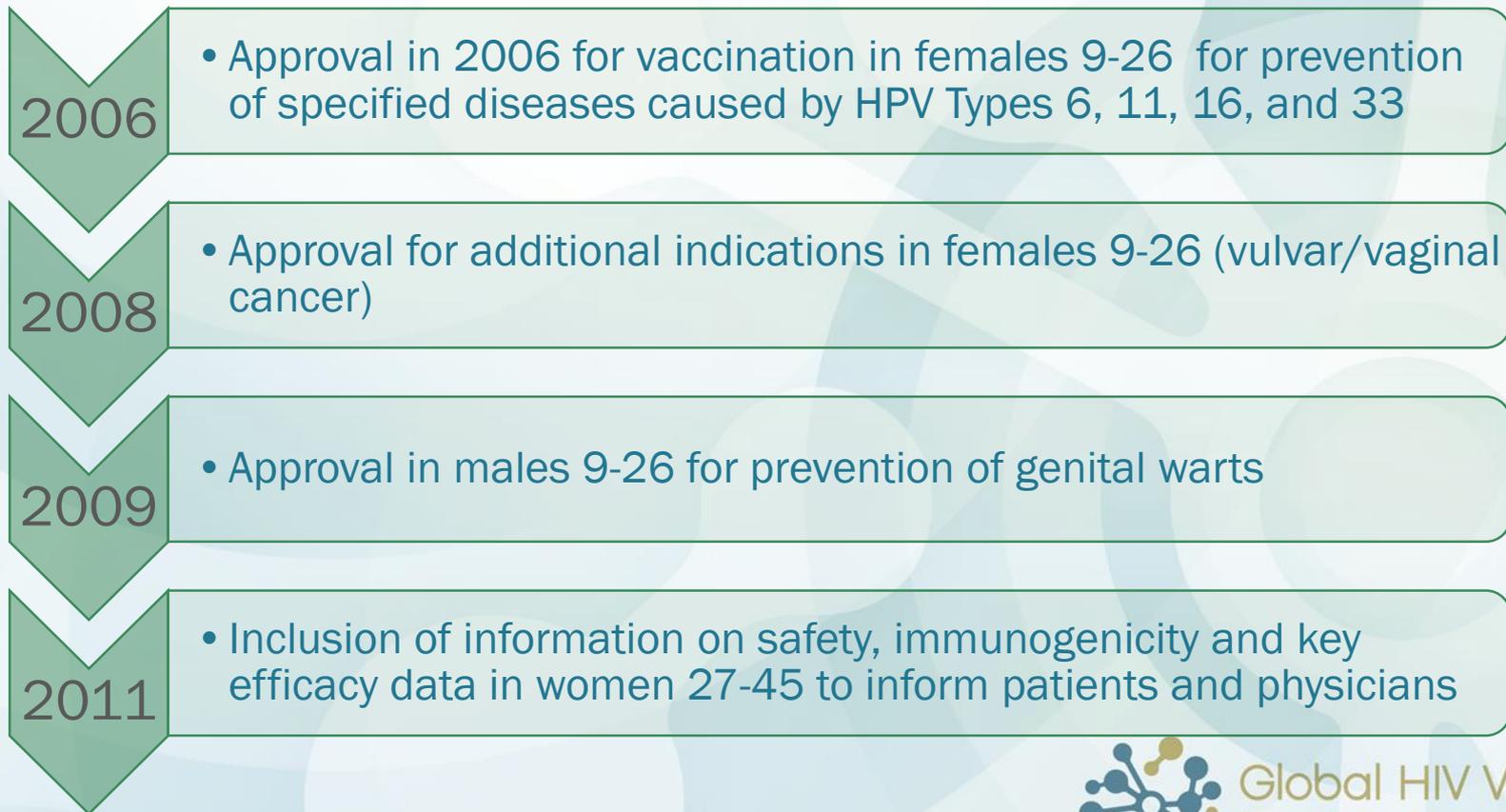
Developing a TPP for an HIV vaccine candidate

- Complex development problem
 - Candidates in clinical trials since the 1980s
 - Multiple candidates and studies completed and ongoing
 - No clear consensus on the required immune response, and what vaccine is needed to drive this response
 - General consensus that relative to other vaccines
 - the vaccine will be complex and multi-component
 - the immunization regimen will involve multiple doses over a long interval

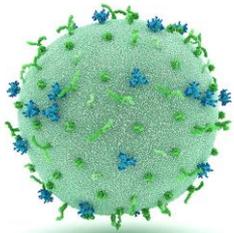


Expanding the indication and target population

Gardasil as an example



Acknowledgement



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