

Brisbane, 14 Sept 2015

### The global roadmap for STI vaccine development: Moving forward

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### STI vaccines are a major priority for sustainable global STI control

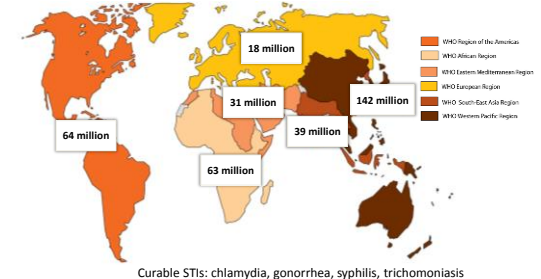
- Large number of infections globally
- Adverse outcomes including HIV risk, infertility, pregnancy complications
- Limitations of existing interventions
- Safe, highly efficacious vaccines against HPV and HBV have been major advances



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### Preliminary WHO estimates: 357 million new cases of curable STIs in 2012



Source: WHO, unpublished data.

### Prevalent HSV-2 estimates: 417 million infections globally in 2012



Source: Looker et al, PLoS ONE, 2015.

### Adverse outcomes

- Syphilis: >300,000 fetal and neonatal deaths per year
- HPV causes >500,000 cases cervical cancer annually
- Chlamydia and gonorrhoea important causes of infertility, ectopic pregnancy
- HSV-2 increases HIV risk by 3-fold
- Genital symptoms and psychosocial consequences have important effects on quality of life



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### Current control challenges

- Limits to progress made with condom promotion
- Most infections asymptomatic and lack of feasible tests in many settings
- Screening programs difficult to bring to scale
- Antimicrobial resistance: drug-resistant gonorrhoea
- Little public policy attention: without simple intervention, harder to garner support



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Highlight need for continued work toward STI vaccine development

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### STI vaccine technical consultation and special issue of *Vaccine*, March 2014



- Need, development status, and future prospects for STI vaccines:
  - HSV
  - Chlamydia
  - Gonorrhoea
  - Syphilis
  - Trichomoniasis
- Global roadmap for STI vaccine development

Available at: <http://www.sciencedirect.com/science/journal/0264410X/32/14>

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### Global roadmap for STI vaccine development

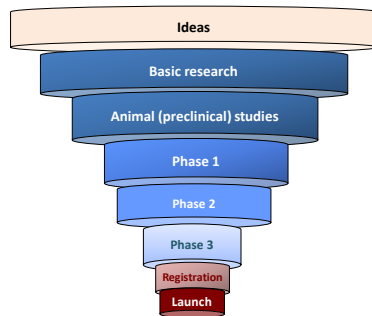


- Consensus based on discussions at consultation
- Critical next steps from pre-vaccine development through vaccine introduction

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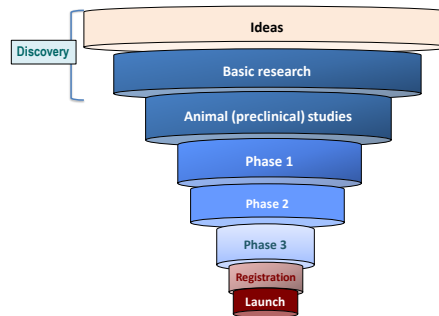


### The vaccine funnel



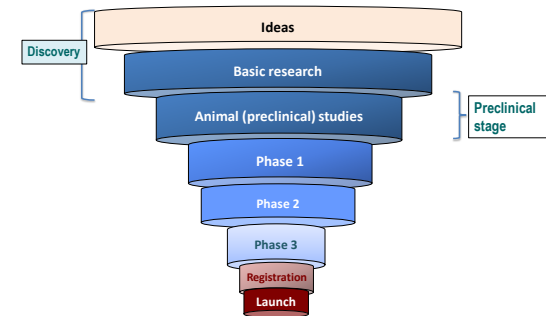
Slide courtesy of Betty Dodet, Dodet Biosciences.

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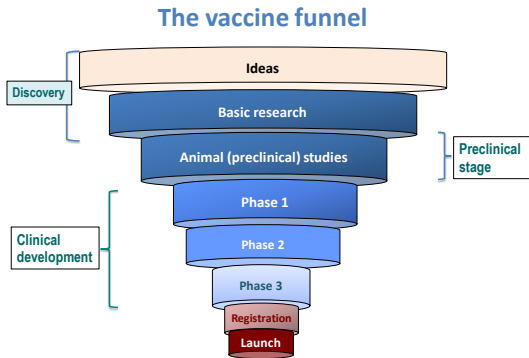


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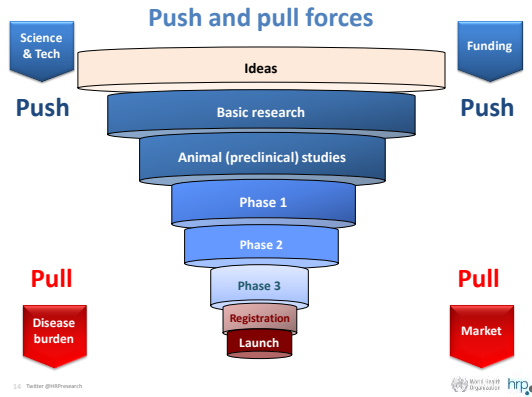
### The vaccine funnel



Slide courtesy of Betty Dodet, Dodet Biosciences.



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### STI vaccine roadmap: 9 priority action areas

1. Obtain better epidemiologic data
2. Improve understanding of STI natural history, burden of sequelae
3. Model the theoretical impact of STI vaccines
4. Advance basic science research for STI vaccines
5. Conduct basic & translational studies in human clinical settings as soon as possible
6. Define preferred product characteristics for 1<sup>st</sup> generation vaccines
7. Expedite clinical development and evaluation
8. Plan for vaccine introduction in advance
9. Encourage investment in STI vaccine development

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### Moving forward: better epidemiologic data

- Update global STI estimates
  - 2015: HSV-2 published; HSV-1, curable STIs under review; neonatal herpes underway
  - HSV-2 added to GBD Study 2013, ongoing updates
  - Continued efforts to improve methods, increase data
- Leverage existing but non-published STI data
  - STIMA: individual participant data meta-analysis
    - Combined data from 18 prospective HIV prevention studies
    - Over 37,000 women in Africa; >95% with STI data
  - Consider: HPV vaccine, circumcision, contraception trials
- Seek opportunities to add STI variables to future studies

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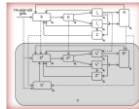
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### Moving forward: STI vaccine modelling

- HSV vaccine modelling meeting, March 2015, reviewed existing models and outlined new modelling needs
  - Inclusion of HIV incidence, neonatal herpes, HSV-1
  - Better primary data on neonatal herpes, costs in LMICs
  - Modelling in different epidemiologic/income settings
- New chlamydia vaccine modelling efforts
  - Owusu-Edusei et al, 2015: suggested a successful chlamydia vaccine could be cost-effective
  - Update as vaccine development advances



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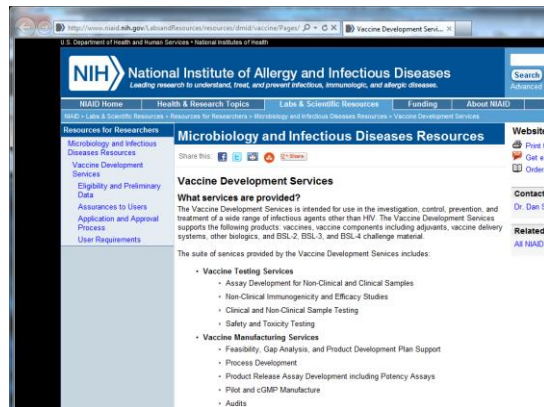
### NIH/NIAID workshops



- Chlamydia vaccine workshop, May 2015
- Gonorrhoea vaccine workshop, June 2015

- Specialized working groups to facilitate collaboration among academics, industry, government
- Standardized reagents, immunogens, assays
- Consensus on most appropriate animal models
- Strategies for how to accelerate moving vaccine candidates into clinical evaluation

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### WHO preferred product characteristics (PPCs)

- Process to reach consensus on characteristics of vaccines meeting priority public health goals for low- and middle-income countries (LMICs)
- Guidance to product developers early in R&D
  - Ensure LMICs will benefit from future vaccine
  - Increase industry confidence in larger global market
  - Shape target product profiles
- Types of characteristics
  - Prophylactic vs therapeutic vaccines
  - Prevention of morbidity vs infection
  - Target population
  - Efficacy requirements
  - Safety and acceptability considerations



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### PD-VAC committee

- HSV vaccine on agenda, presented at September 2015 PD-VAC meeting
- Discussed how WHO could facilitate development
  - Consensus building on possible role of vaccines in pipeline in LMICs, clinical trial endpoints, PPCs
  - How to obtain better data on neonatal herpes in LMICs
  - Updated modelling efforts



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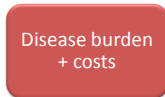
### Comprehensive vaccine business case

- Single document pulling together many aspects of roadmap to:
  - Guide investment
  - Inform decision-making
  - Outline public health rationale

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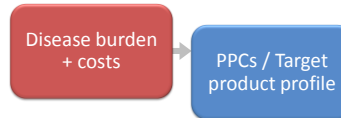
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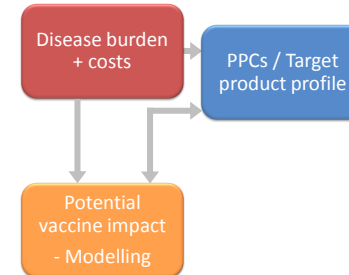
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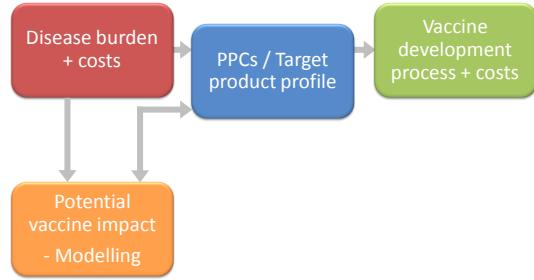
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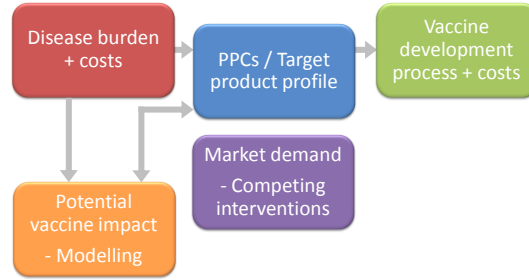
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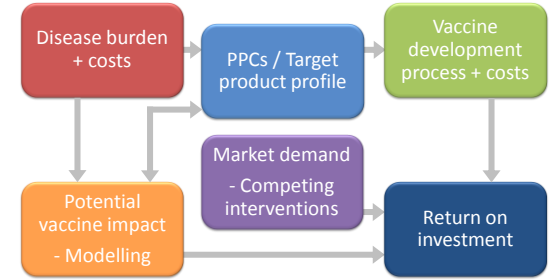
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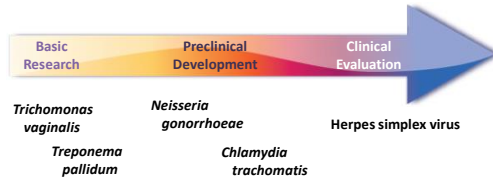
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Current status of the development pathway of STI vaccines



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Thank you!

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 Carolyn Deal  
 Gitte Giersing  
 Helen Rees  
 STI Vaccine Technical Consultants

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