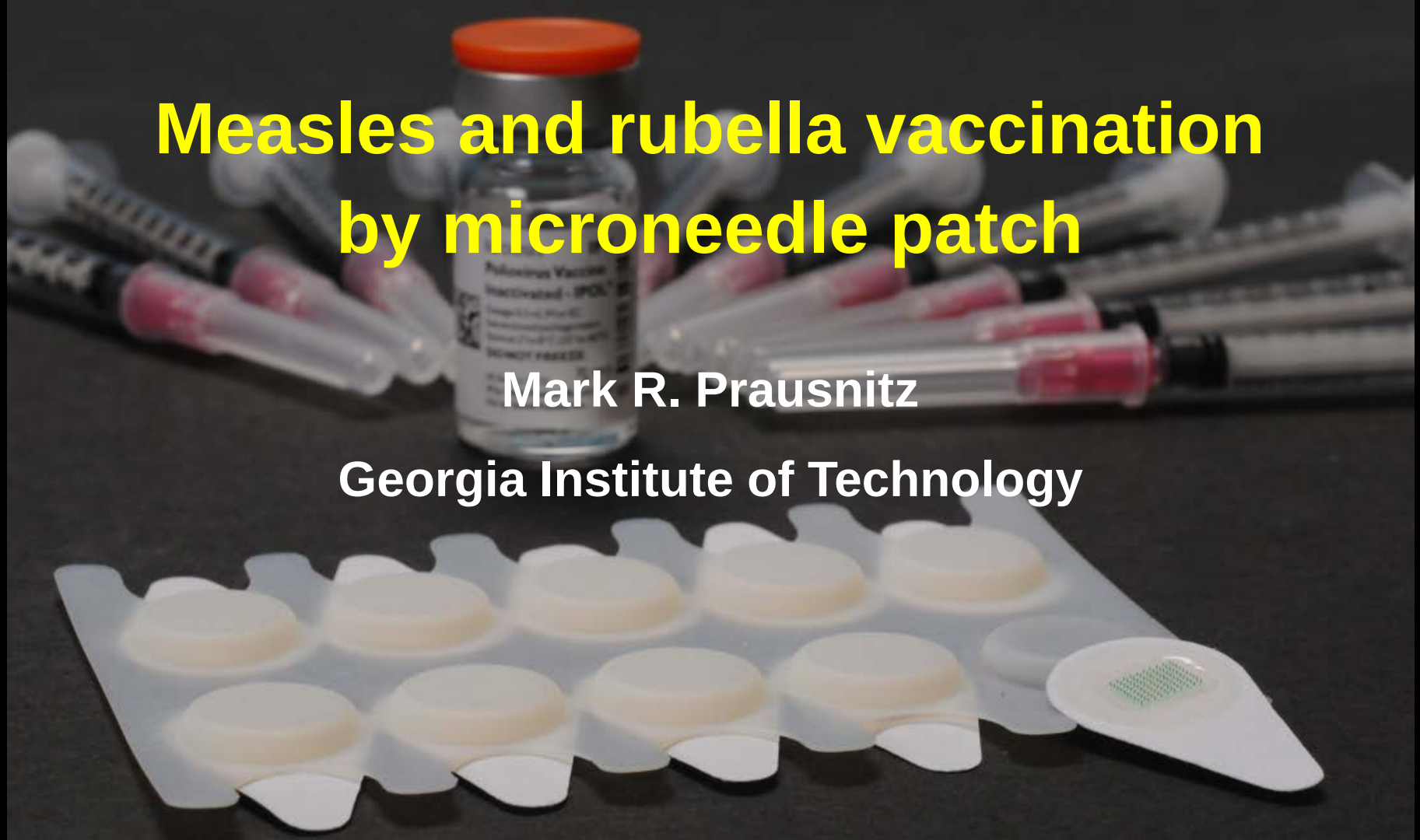
Measles and rubella vaccination by microneedle patch



Mark R. Prausnitz

Georgia Institute of Technology

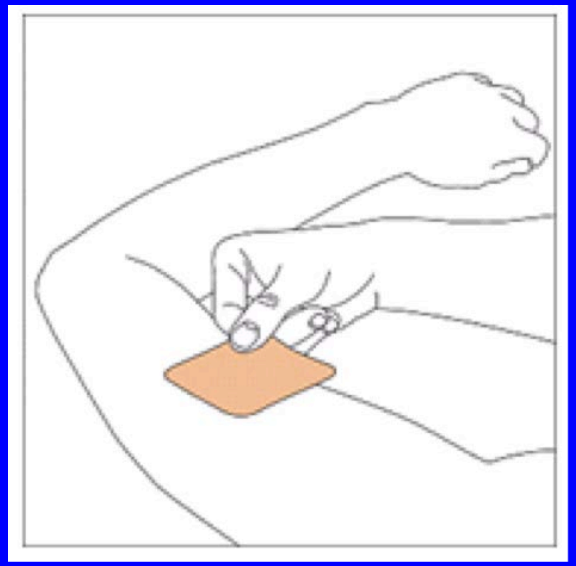
Disclosure

Mark Prausnitz is a co-founder and has a significant financial interest in Micron Biomedical.

This conflict of interest is managed by Georgia Tech and Emory University.

Outline

Development of the MR patch

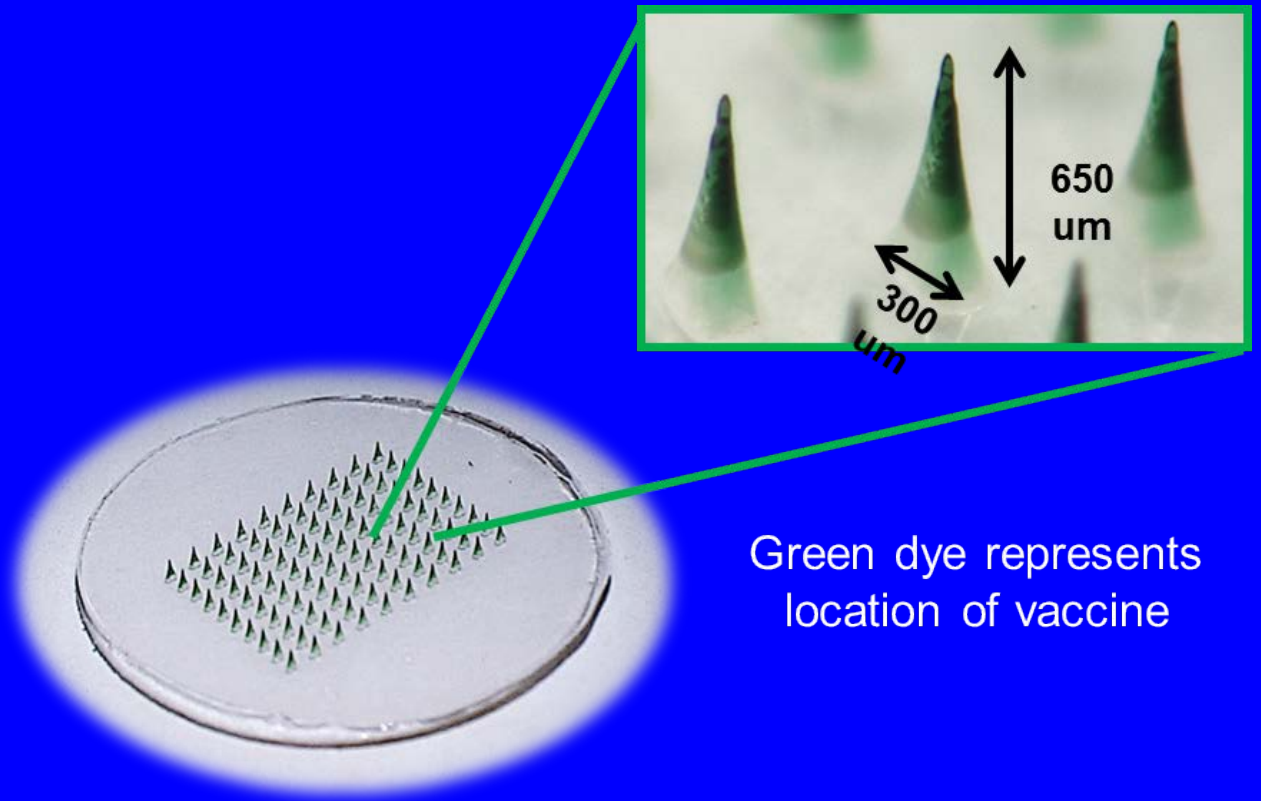


The path to clinical trial and licensure

Dissolving microneedle patch

Dissolving microneedle patch

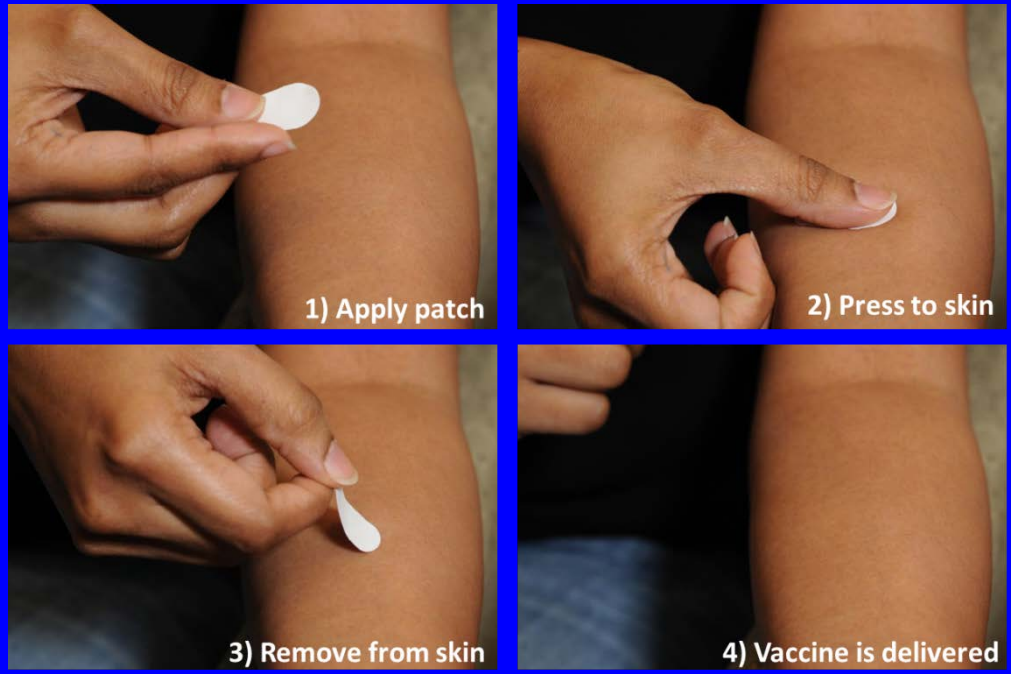
Dissolving microneedle patch



Microneedle patch meets public health needs

Patient administration

- Minimally-trained personnel
- No applicator, no reconstitution
- Painless delivery, no fear of needle



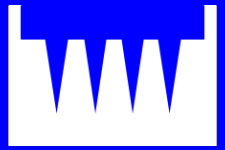
Microneedle patch meets public health needs

Patient administration

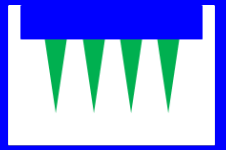
- Minimally-trained personnel
- No applicator, no reconstitution
- Painless delivery, no fear of needle

Manufacturing

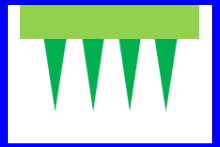
- Low-cost, scalable fabrication



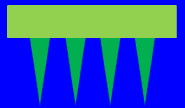
Prepare microneedle mold



Cast antigen formulation into micromold cavities



Cast matrix formulation onto micromold surface



Dry and remove microneedle patch

Microneedle patch meets public health needs

Patient administration

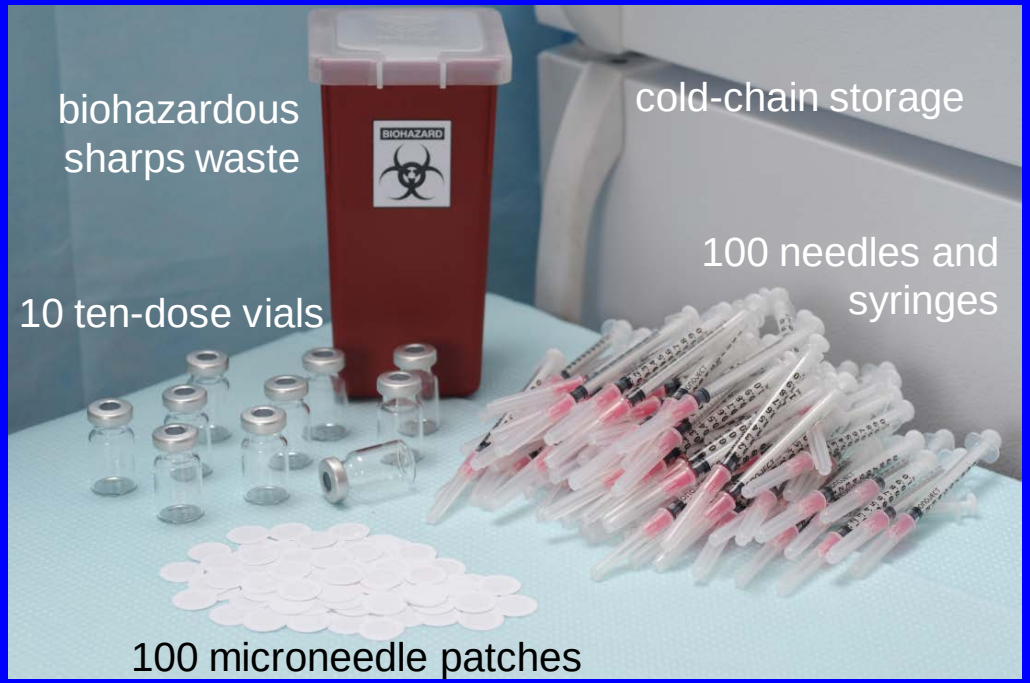
- Minimally-trained personnel
- No applicator, no reconstitution
- Painless delivery, no fear of needle

Manufacturing

- Low-cost, scalable fabrication

Transportation and storage

- Small package size
- Improved thermostability



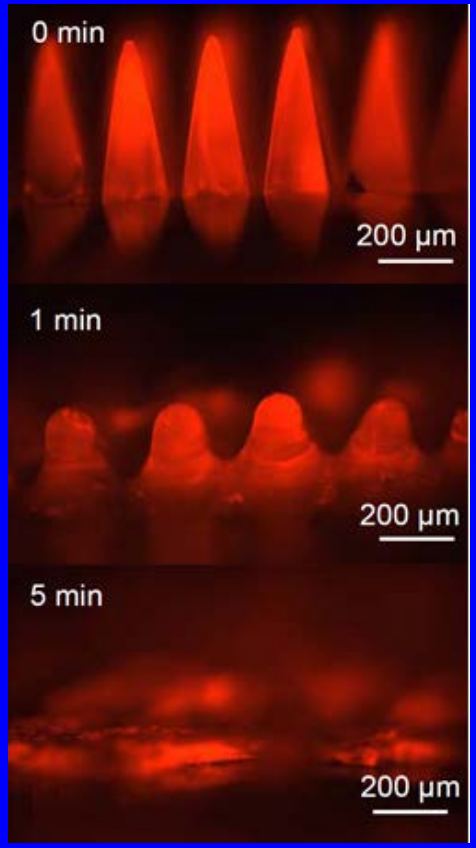
Microneedle patch meets public health needs

Patient administration
- Minimally-trained personnel
- No applicator, no reconstitution
- Painless delivery, no fear of needle

Manufacturing
- Low-cost, scalable fabrication

Transportation and storage
- Small package size
- Improved thermostability

Waste disposal
- Impossible reuse
- Reduced disposal volume



Micron Biomedical

Commercializing Georgia Tech microneedle patch technology

Partners
- **BMGF, UNICEF, CDC**
- **Pharmaceutical companies**

Clinical stage
- **GMP manufacturing (e.g., MR patch)**
- **Regulatory filings**

Commercial manufacturing
- **Clinical trial materials**
- **Pilot manufacturing line designed**
- **Commercial manufacturing line designed**

Micron Biomedical

Target product profile

Indication:	**Measles and rubella prophylaxis**
Target population:	**Age 9-months and older**
Uses:	**Routine immunization** **Supplementary immunization activities** **Outbreak response immunization**
Safety:	**AEs no more serious than current MR vaccines**
Reactogenicity:	**Mild, transient erythema and pruritus**
Immunogenicity:	**Seroconversion non-inferior to current MR vaccines**

Target product profile

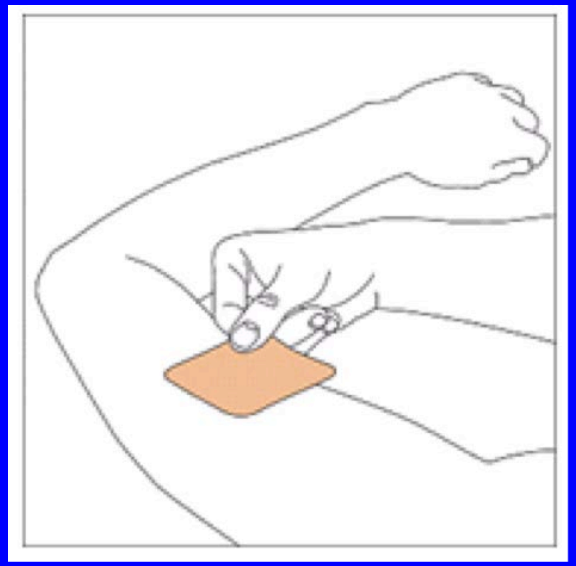
Presentation:	**Single dose, single use** **Integrated vaccine delivery system**
Route of admin.:	**Skin**
Application:	**No applicator required**
User training:	**No training, minimal instructions**
Wear time:	**1 – 5 minutes**
Delivery indicator:	**Auditory and visual**
Disposal:	**Non-sharps, biohazardous waste** **Reduced volume**

Target product profile

Stability:	**VVM14 (2-8°C @ 24 months, 40°C @ 3 days)**
Product registration pathway:	**WHO pre-qualification**
Cost per immunized child:	**Possible increased COGS offset by programmatic savings**

Outline

Development of the MR patch



The path to clinical trial and licensure

Timeline of MR patch development

2009 WHO grant (IPV patch)

2011 WHO and BMGF grants (IPV patch)

Georgia Tech

CDC
Centers for Disease Control and Prevention

World Health Organization

Bill & Melinda Gates foundation

Timeline of MR patch development

2009 WHO grant (IPV patch)

2011 WHO and BMGF grants (IPV patch)

2013 Measles patch in cotton rats

2015 Measles patch in NHP

2018 MR patch in infant NHP

Measles vaccination using a microneedle patch☆

Chris Edens[a], Marcus L. Collins[b], Jessica Ayers[d], Paul A. Rota[b,**], Mark R. Prausnitz[a,c,*]

[a] Coulter Department of Biomedical Engineering at Georgia Tech and Emory University, Georgia Institute of Technology, Atlanta, GA 30332, United States
[b] Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, GA 30333, United States
[c] School of Chemical and Biomolecular Engineering, Georgia Institute of Technology, Atlanta, GA 30332, United States
[d] Animal Research Branch, Division of Scientific Resources, Centers for Disease Control and Prevention, Atlanta, GA 30333, United States

Vaccine 31 (2013) 3403–3409

A microneedle patch containing measles vaccine is immunogenic in non-human primates

Chris Edens[a], Marcus L. Collins[b,1], James L. Goodson[c,1], Paul A. Rota[b,*,1], Mark R. Prausnitz[a,d,**]

[a] Coulter Department of Biomedical Engineering at Georgia Tech and Emory University, Georgia Institute of Technology, Atlanta, GA 30332, USA
[b] National Center for Immunization and Respiratory Diseases, Division of Viral Diseases, Centers for Disease Control and Prevention, Atlanta, GA 30329, USA
[c] Center for Global Health, Global Immunization Division, Centers for Disease Control and Prevention, Atlanta, GA 30329, USA
[d] School of Chemical and Biomolecular Engineering, Georgia Institute of Technology, Atlanta, GA 30332, USA

Vaccine 33 (2015) 4712–4718

A Microneedle Patch for Measles and Rubella Vaccination Is Immunogenic and Protective in Infant Rhesus Macaques

Jessica C. Joyce,[1,a] Timothy D. Carroll,[2] Marcus L. Collins,[3] Min-hsin Chen,[3] Linda Fritts,[2] Joseph C. Dutra,[2] Tracy L. Rourke,[2] James L. Goodson,[3] Michael B. McChesney,[2] Mark R. Prausnitz,[1,4] and Paul A. Rota[3]

[1]Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology, Atlanta; [2]Center for Comparative Medicine, and California National Primate Research Center, University of California, Davis, CA; and [3]Centers for Disease Control and Prevention, Atlanta, GA and [4]School of Chemical and Biomolecular Engineering, Georgia Institute of Technology, Atlanta, GA

The Journal of Infectious Diseases® 2018;218:124–32

Timeline of MR patch development

2009 WHO grant (IPV patch)

2011 WHO and BMGF grants (IPV patch)

2013 Measles patch in cotton rats

2015 Measles patch in NHP

2017 Phase 1 clinical trial (influenza patch)

2018 MR patch in infant NHP

The safety, immunogenicity, and acceptability of inactivated influenza vaccine delivered by microneedle patch (TIV-MNP 2015): a randomised, partly blinded, placebo-controlled, phase 1 trial

Nadine G Rouphael, Michele Paine, Regina Mosley, Sebastien Henry, Devin V McAllister, Haripriya Kalluri, Winston Pewin, Paula M Frew, Tianwei Yu, Natalie J Thornburg, Sarah Kabbani, Lilin Lai, Elena V Vassilieva, Ioanna Skountzou, Richard W Compans, Mark J Mulligan*, Mark R Prausnitz*, for the TIV-MNP 2015 Study Group†

Lancet 2017; 390: 649–58

Timeline of MR patch development

- 2009 WHO grant (IPV patch)
- 2011 WHO and BMGF grants (IPV patch)
- 2013 Measles patch in cotton rats
- 2015 Measles patch in NHP
- 2016 BMGF grant (MR patch)
- 2017 Phase 1 clinical trial (influenza patch)
- 2018 MR patch in infant NHP
- 2019 Ready for clinical trial

Georgia Tech

CDC
Centers for Disease Control and Prevention

Poonawalla Group
Serum Institute of India Pvt. Ltd.

Micron Biomedical

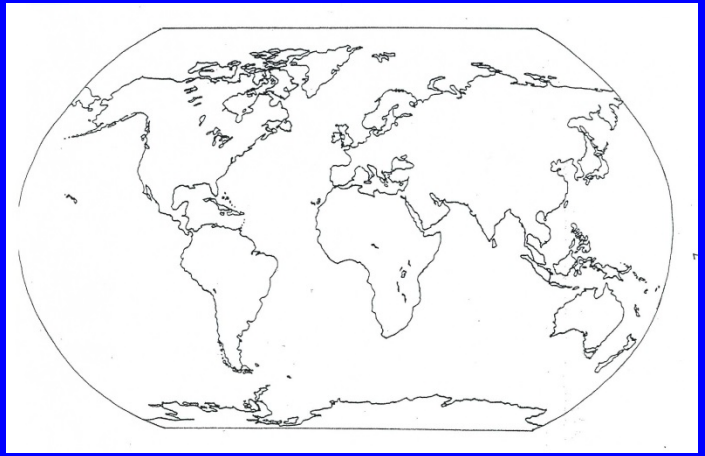
Bill & Melinda Gates foundation

unicef

Phase 1 clinical trial of MR patch

Study site:

Developing country, USA, Europe



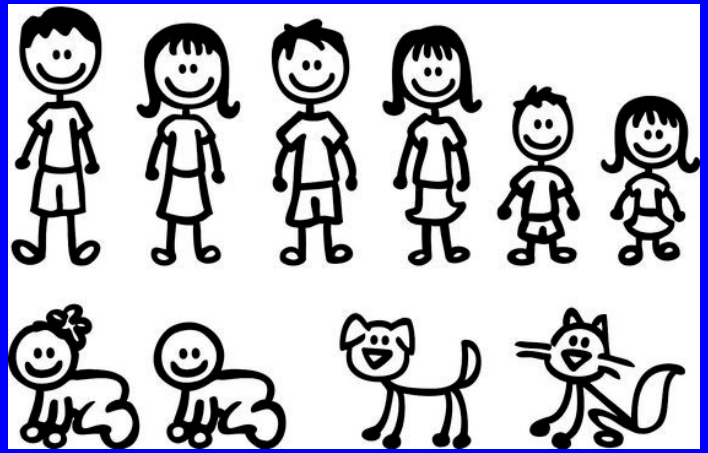
Phase 1 clinical trial of MR patch

Study site:

Developing country, USA, Europe

Study population:

Adults only, adults and infants

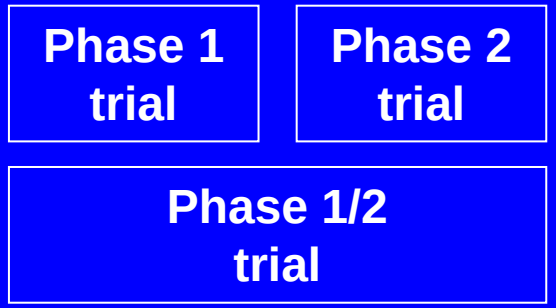


Phase 1 clinical trial of MR patch

Study site:
Developing country, USA, Europe

Study population:
Adults only, adults and infants

Clinical phase:
Phase 1, Phase 1/2



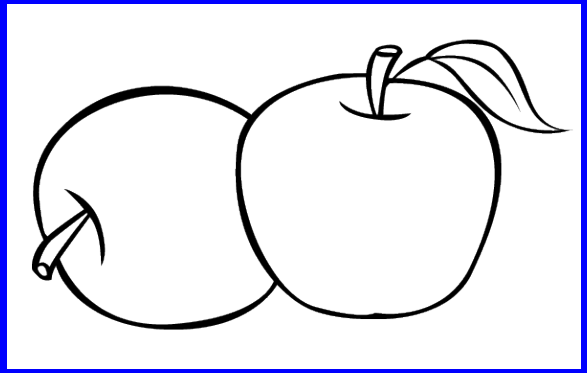
Phase 1 clinical trial of MR patch

Study site:
Developing country, USA, Europe

Study population:
Adults only, adults and infants

Clinical phase:
Phase 1, Phase 1/2

Stage gate:
ASAP, “apples-to-apples”

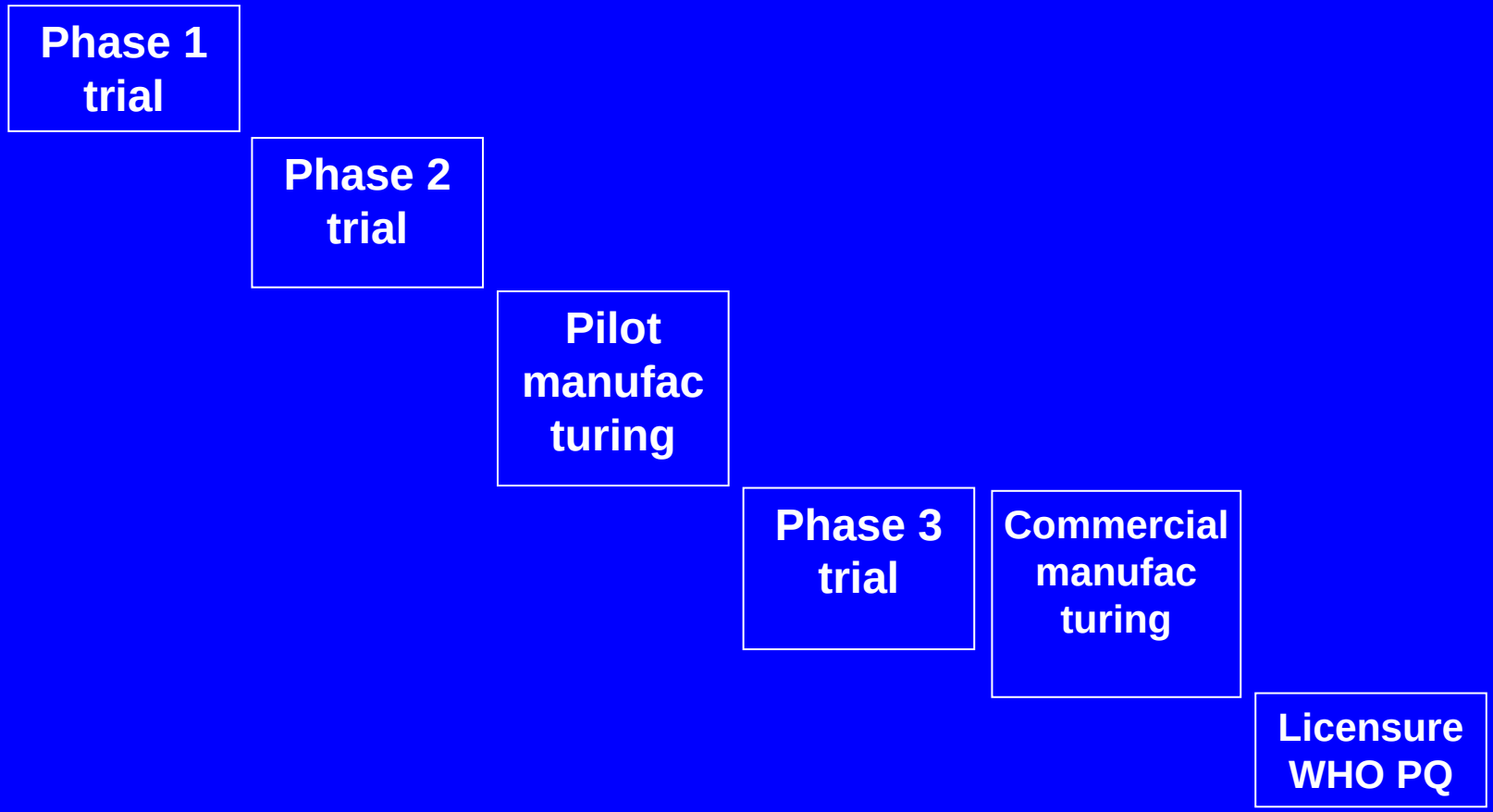


Risk

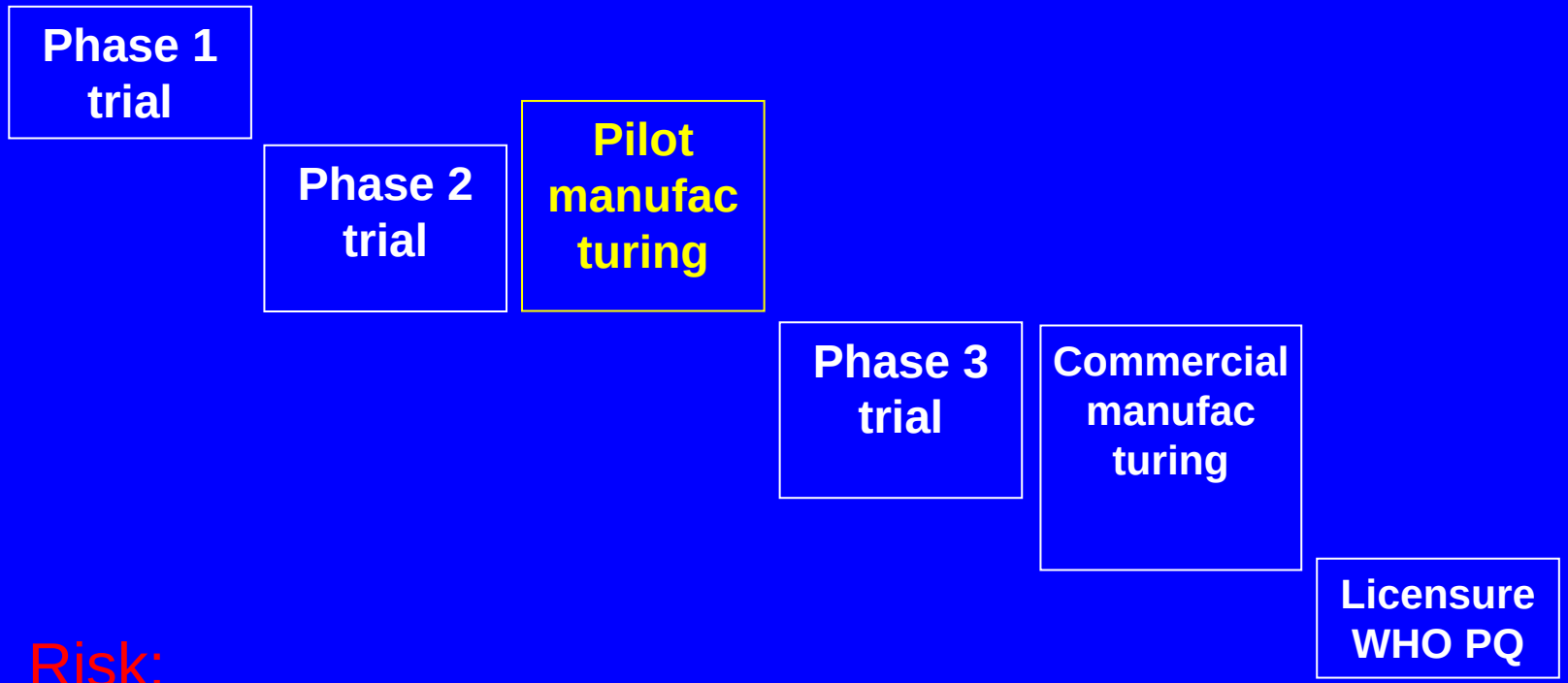
vs.

Speed

Timeline of MR patch development



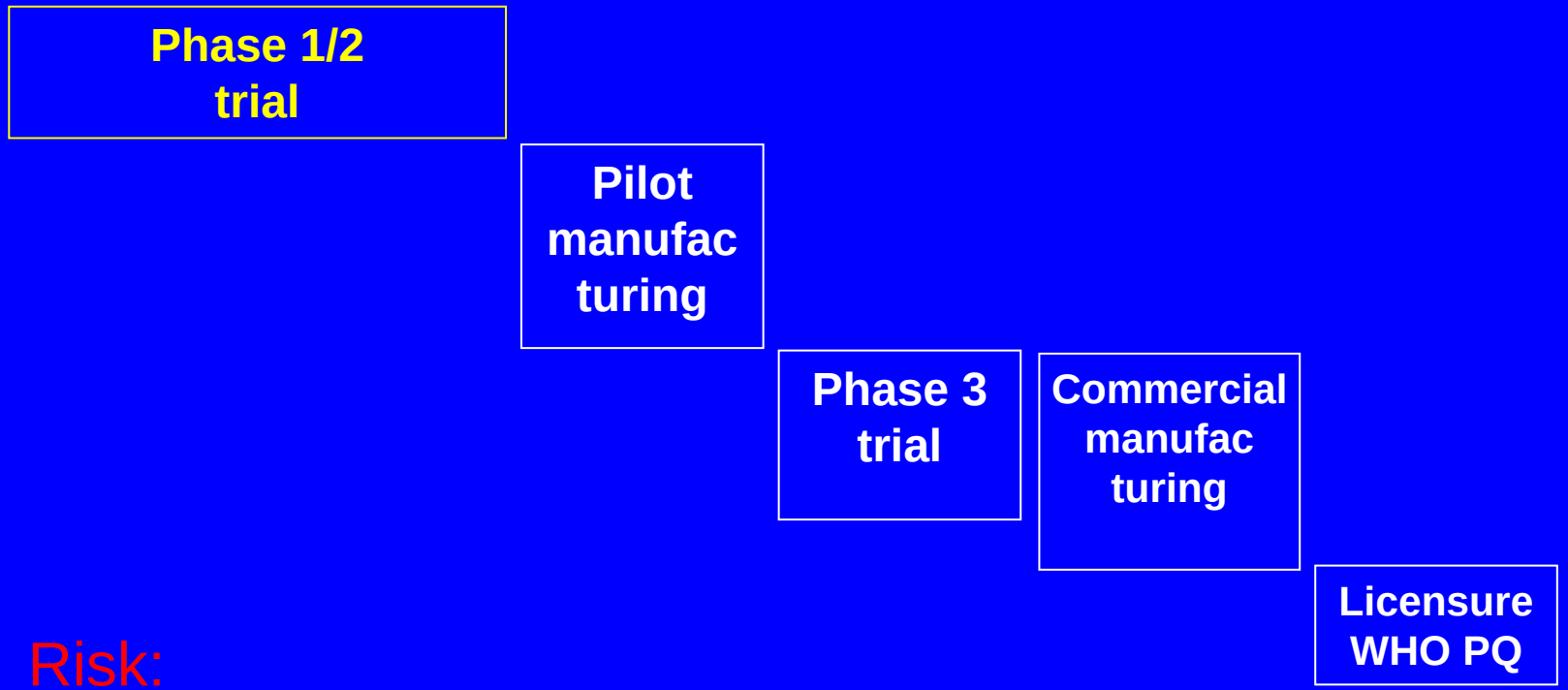
Timeline of MR patch development



Risk:

Invest in pilot manufacturing before clinical trial results

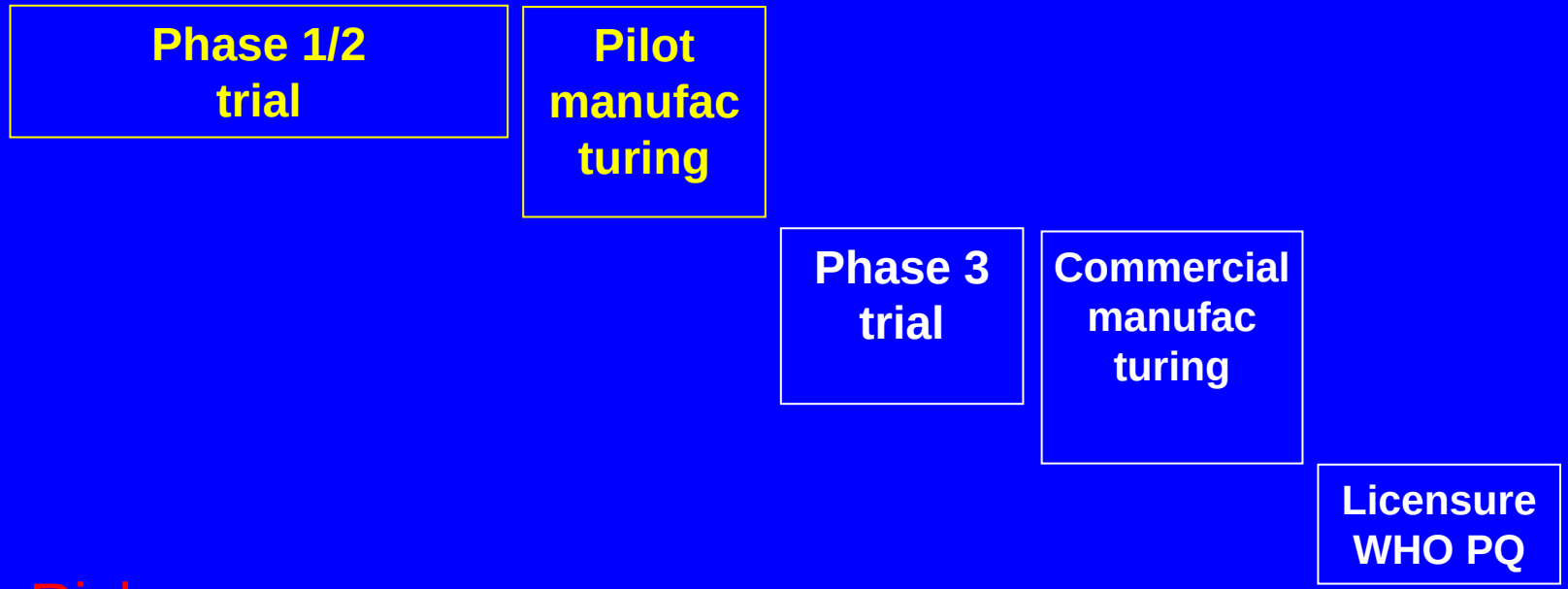
Timeline of MR patch development



Risk:

Only one clinical trial before Phase 3 trial

Timeline of MR patch development



Risk:

Invest in pilot manufacturing before clinical trial results

Only one clinical trial before Phase 3 trial


Questions?