# Leveraging Innovation to Improve Patient Access & Global Health

CASSS

Well Characterized Biological Products

David Robinson

Bill & Melinda Gates Foundation


WE ENVISION A
WORLD WHERE
EVERY
PERSON
HAS THE OPPORTUNITY
TO LIVE A HEALTHY,
PRODUCTIVE LIFE


ALL LIVES HAVE
EQUAL
VALUE

# OUR GLOBAL REACH AND PRESENCE


**$40B**
Trust endowment

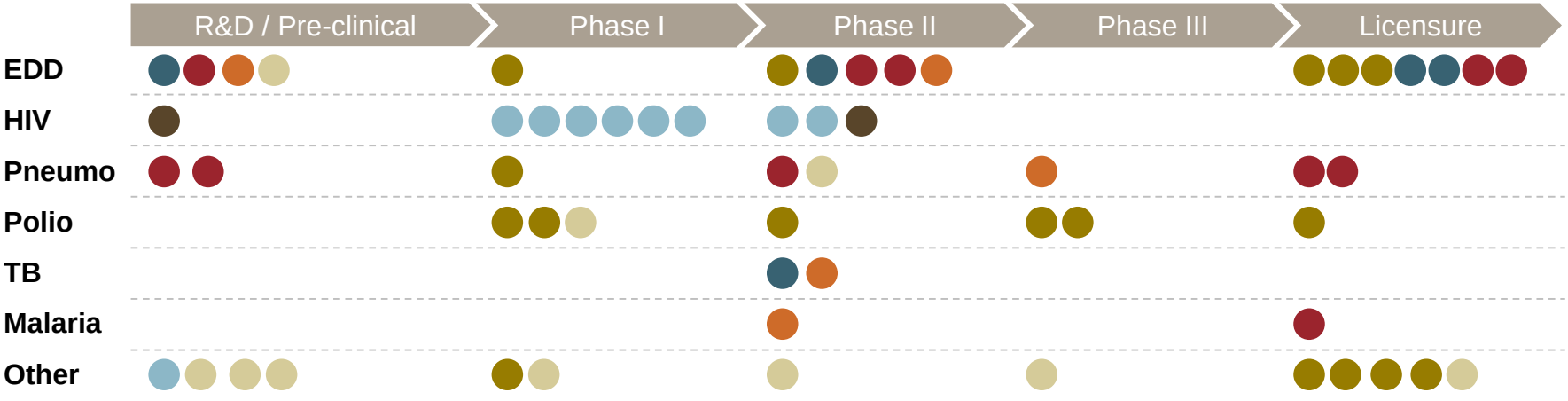
**1,500+**
2016 active grantees

**$4.3B**
2016 grant payments

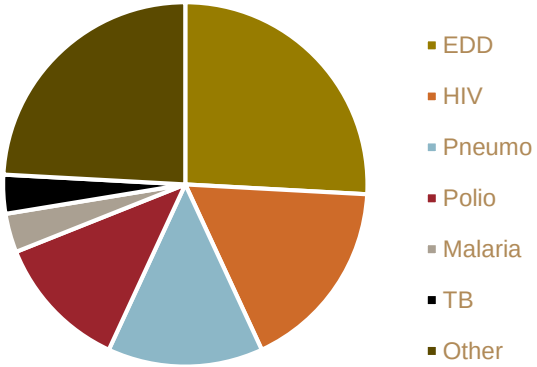
**1,400+**
2016 employees worldwide

UNITED STATES PROGRAM | GLOBAL HEALTH | GLOBAL DEVELOPMENT

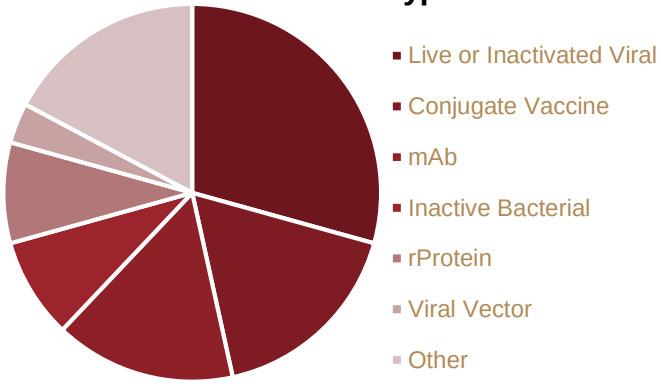
# OUR VACCINE & ANTIBODY PORTFOLIO




**Distribution of Portfolio by Program Area**




**Distribution of Portfolio by Vaccine Type**




- Live/Inactivated Viral
- rProtein
- Antibody
- Conjugate Vaccines
- Viral Vector
- Inactivated Bacterial
- Combination
- Other

# GLOBAL NUMBER OF DEATHS OF CHILDREN UNDER AGE FIVE

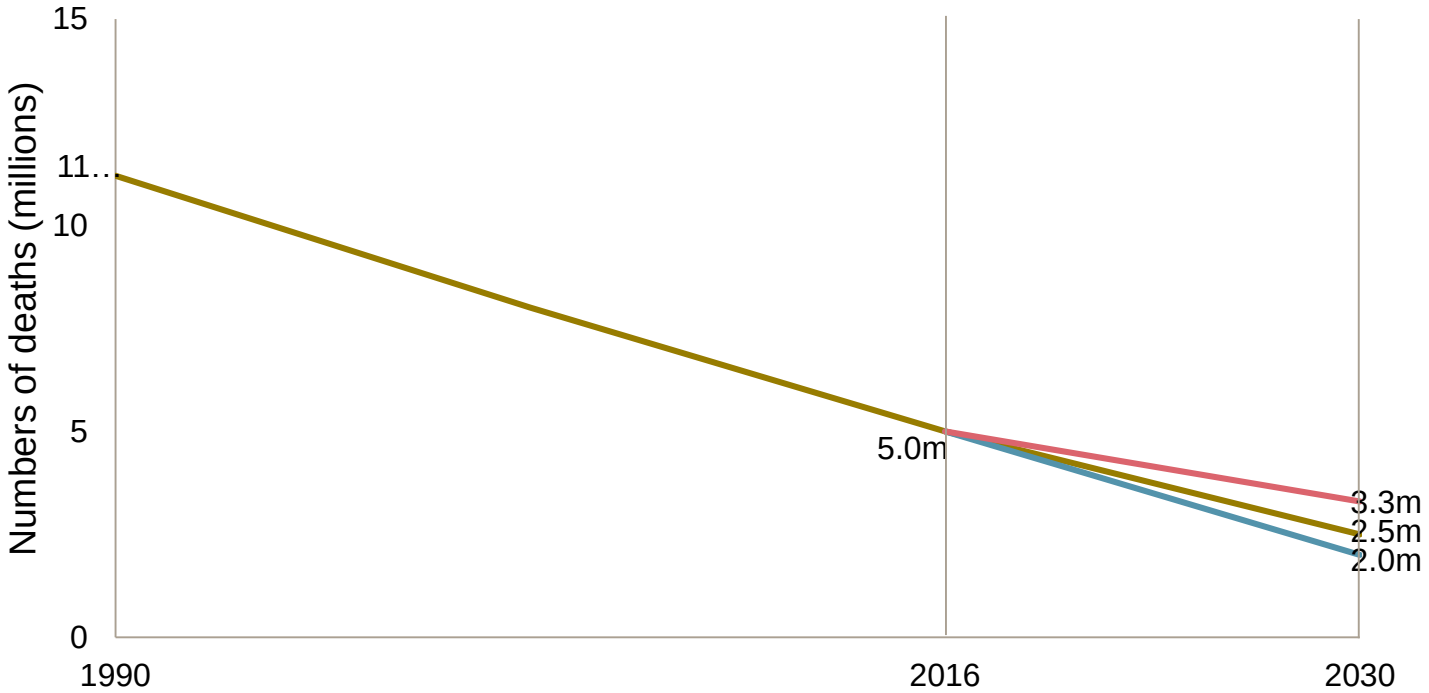
**Drivers of progress**

Improvements in

- Maternal education
- Income growth
- New drugs, vaccines and other health innovations

Driven by

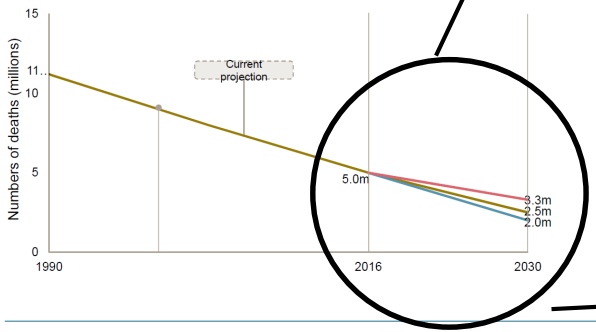
- Increases in donor spending

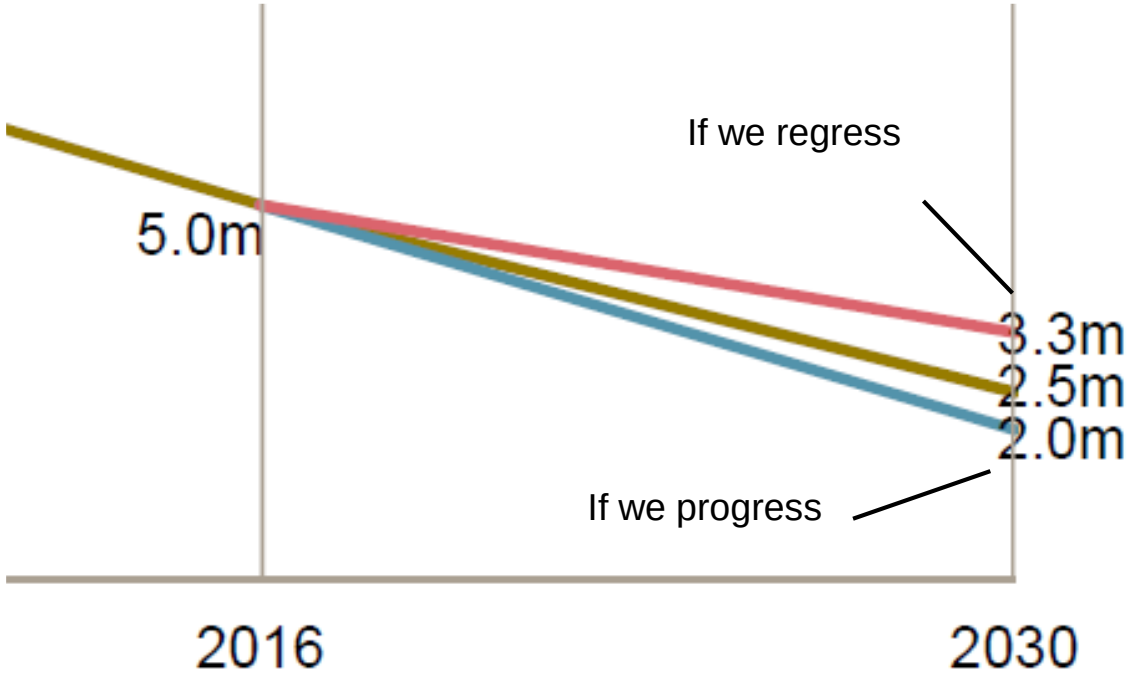



https://www.globalgoals.org/goalkeepers, accessed May 1, 2018; www.healthdata.org; IHME accessed 13MAY2018

# GLOBAL NUMBER OF DEATHS OF CHILDREN UNDER AGE FIVE

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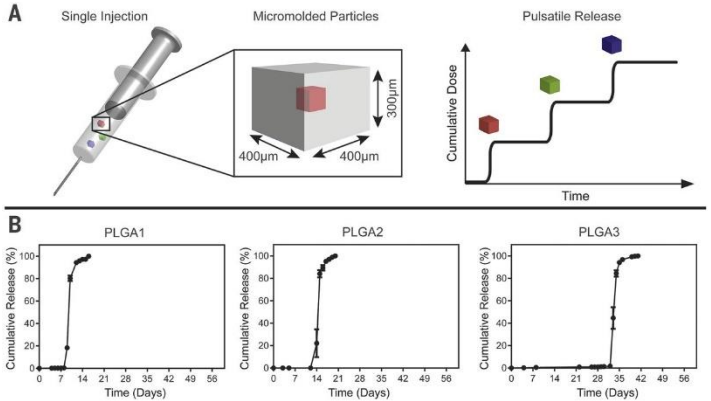
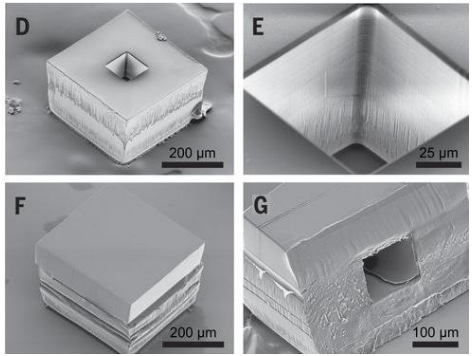
# WHAT ROLE CAN INNOVATORS IN TECHNOLOGY AND REGULATORY PLAY

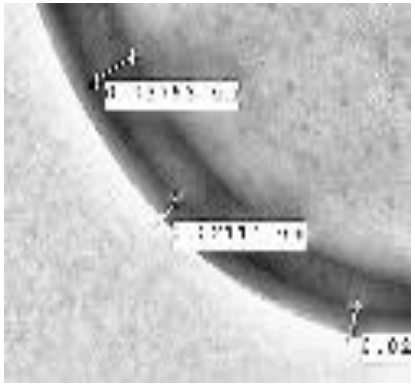
- Increase coverage by making vaccination easier
  - Reduce number of injections that a child needs to receive
- Increase access by reducing the cost of vaccination
  - Lower the capital costs of new facilities
  - Improve the accuracy of potency assays to reduce the overfill
- Enable the adoption of new technologies
  - Close regulatory interactions with technical developers
  - Streamlining and harmonizing regulatory policies across the globe

# REDUCING THE NUMBER OF INJECTIONS VIA PULSATILE RELEASE FOR MULTI-DOSE VACCINES



*Cup-Shell Microparticles*
*McHugh, Janklevec, Langer*
*MIT*

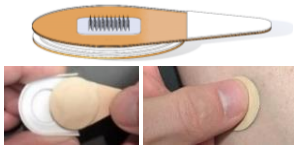
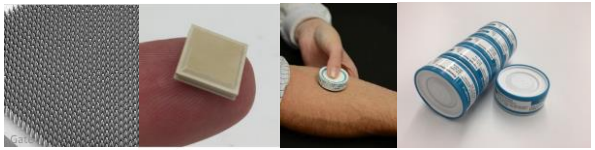
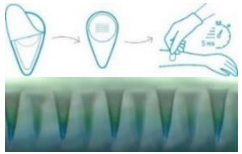
*Atomic-Layer Deposition,*
*Garcea, Randolph*
*Weimer*
*U. C. Boulder*

https://www.colorado.edu/research/report/2016-17/shot-arm
Kevin J. McHugh et al. Science 2017;357:1138-1142

# MAKING VACCINE SUPPLY AND ADMINISTRATION EASIER

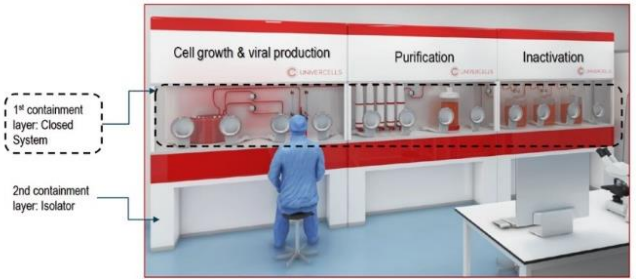
MAPS could enable house-to-house campaigns if:

- More thermostable
- Delivered by lower-skilled heath-care worker
- Non-inferior immunogenicity
- Appropriate cost

| Grantee | Image and description of MAP | |
|---|---|---|
| "Peel-and-stick" (Georgia Institute of Technology, Micron Biomedical) |  | **Dissolving** MAP with **audible force-feedback indicator** |
| Nanopatch (vaxxas) |  | **Coated polymer** MAP with **single-use spring applicator** |
| Mimix (VAXESS technologies) |  | **Dissolving MAP** made of **silk** protein with **audible force-feedback indicator** |

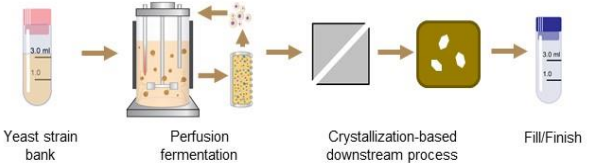
# REDUCING COSTS VIA MODULAR FACILITIES, PROCESS INTENSIFICATION AND PROCESS INTEGRATION

**Viral Vaccines: NevoLine™**

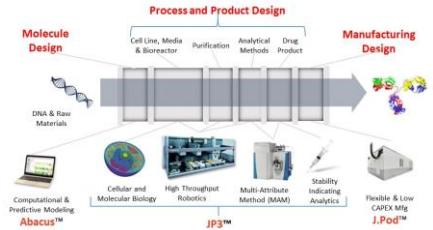



- **NevoLine™** uses compact bioreactor and membranes for semi-continuous production of **viral vaccines**
  - Prototype compact enough to fit in isolator enabling production of sIPV
  - First microfacility will be built and installed in 2018

- **ULTRA** uses strain engineering and process intensification to reduce costs for making recombinant **protein based vaccines**
  - Targeting manufacturing costs of $0.15 per dose




**mAbs: Just**



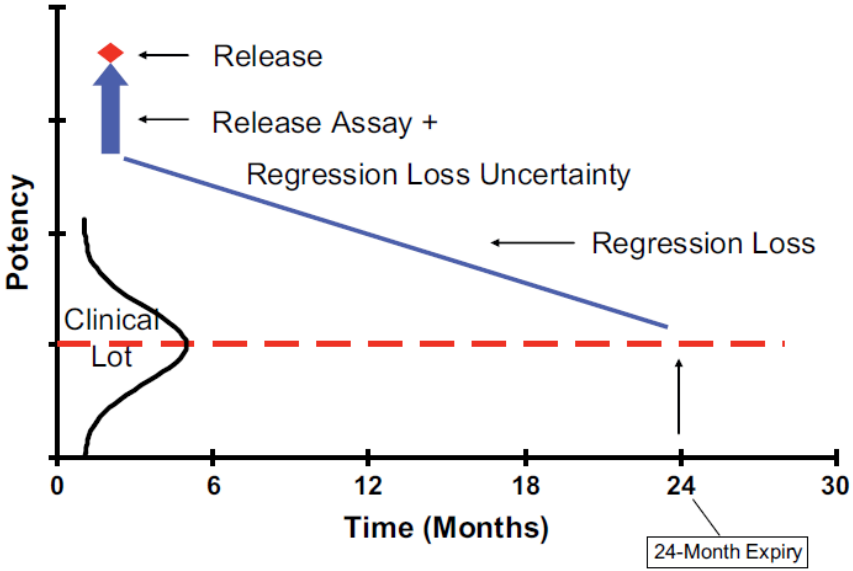

- **Just** uses design database to optimize **antibodies** for manufacturability and process intensification to reduce manufacturing costs and facility footprint & cost
  - HIV broadly neutralizing antibodies optimized for high productivity and formulation at high concentrations required for subcutaneous administration

# REDUCE COSTS BY REDUCING OVERAGE

Some of the more labile, and difficult to assay, vaccines have overages of nearly ten-fold to account for the uncertainty of the potency assays and loss of potency upon storage

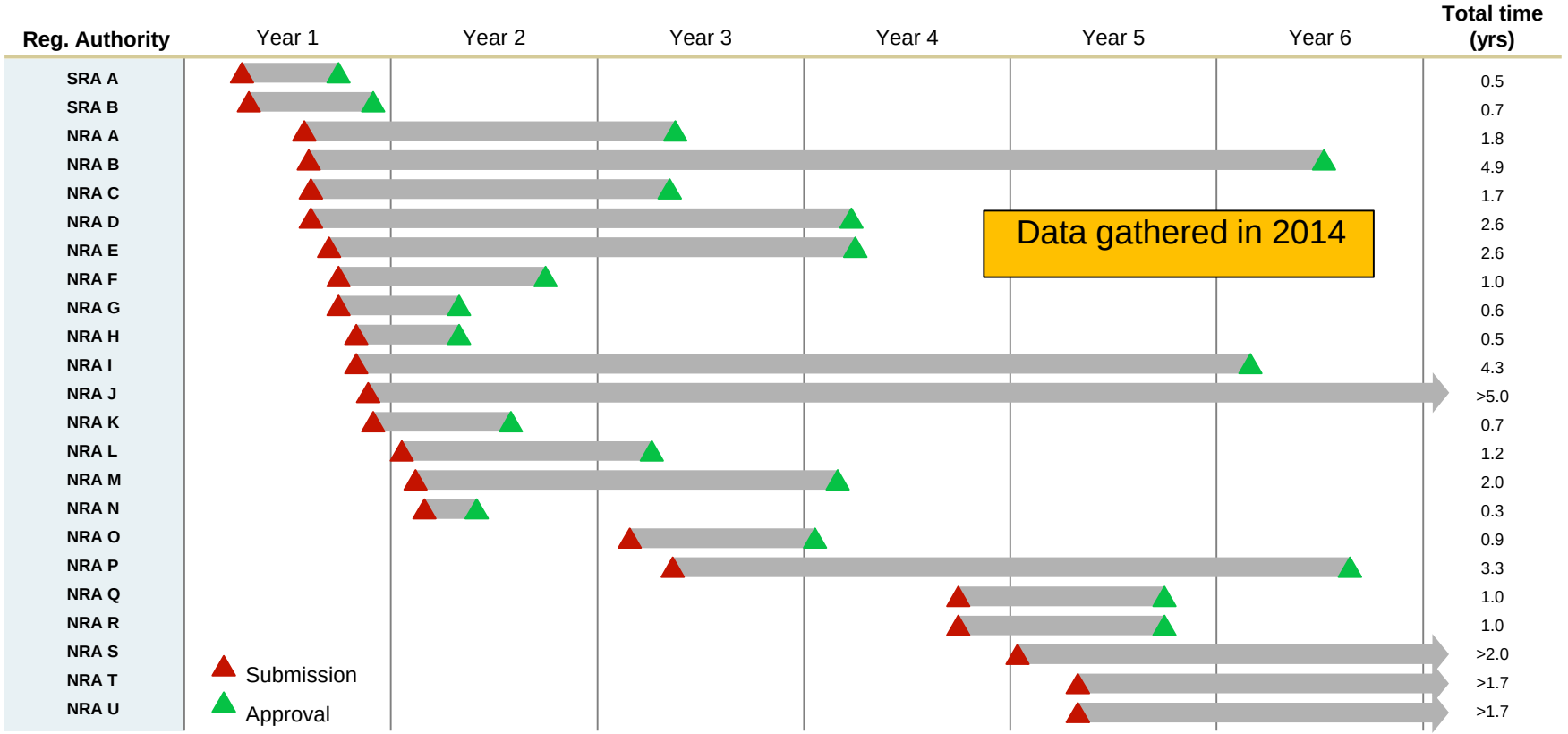
Investing in technologies to increase the precision of potency assays and improve thermostability for vaccines

Potential to reduce overage and reduce costs




*T.L. Schofield / Biologicals 37 (2009) 387–396*

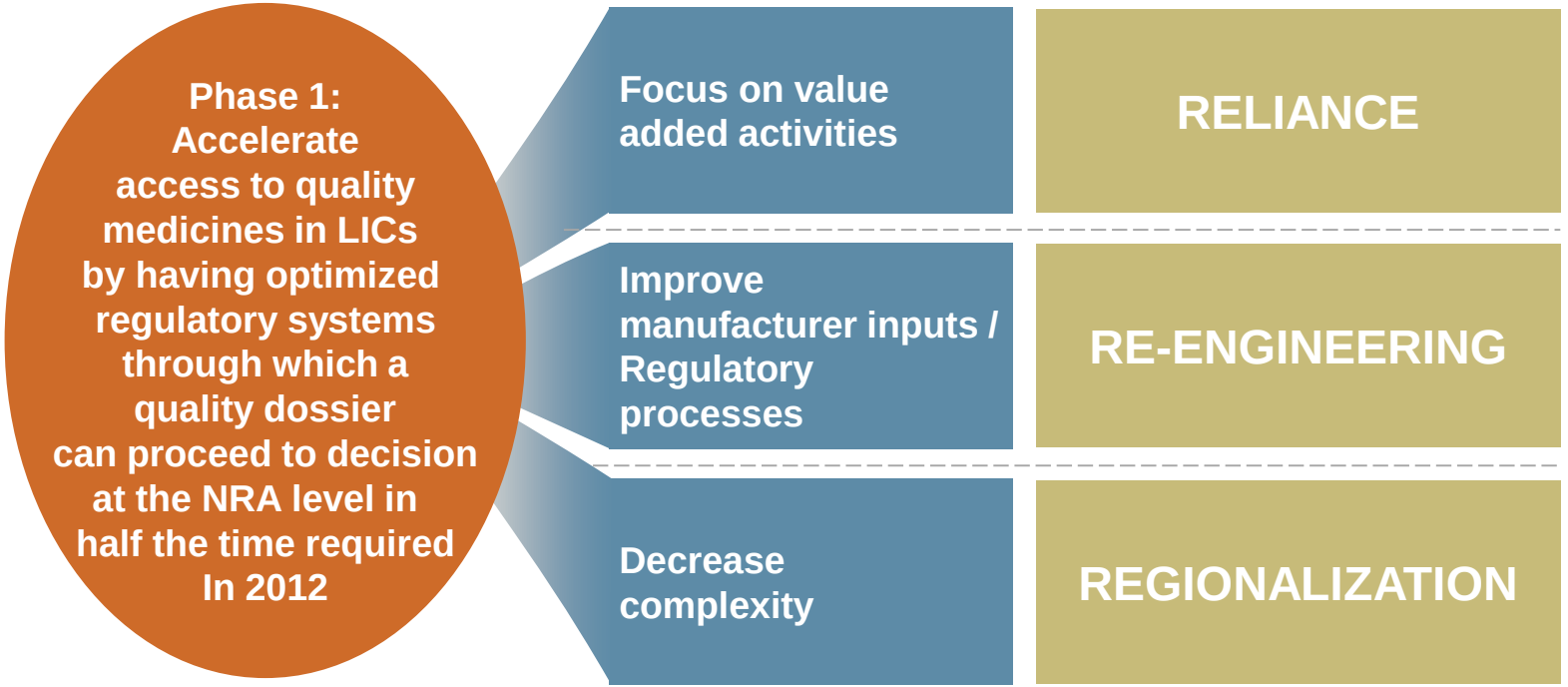
# CAN TAKE A LONG TIME TO GET NEW PRODUCTS, AND NEW TECHNOLOGIES, APPROVED AROUND THE GLOBE




Source: BMGF Regulatory Strategy study

# FOUNDATION IS WORKING WITH WHO AND MULTIPLE NATIONAL REGULATORY AGENCIES ON A STRATEGY




**Phase 2:**
**Expand Impact**

# THE FOUNDATION HAS PARTNERED WITH NIIMBL TO SET UP A COLLABORATION FOR GLOBAL HEALTH


*The National Institute for Innovation in Manufacturing and Biopharmaceuticals was developed under the US National Institute of Standards and Technology*

**How we want to work together:**

- Collaborate to de-risk technologies of mutual interest to global health and broader biopharmaceutical industry
- Introduce global health challenges to NIIMBL membership of academics, pharmas and biotech
- Joint funding of priority programs through RFP call
- Partner on solutions for workforce development and regulatory engagement

# TECHNOLOGIES ARE ONLY ONE ELEMENT OF ACCELERATING DEVELOPMENT: HOLISTIC UNDERSTANDING IS REQUIRED