PATH's Experience from Jet Injector R&D and Field Assessment in Developing Countries

Innovative Administration Systems for Vaccines

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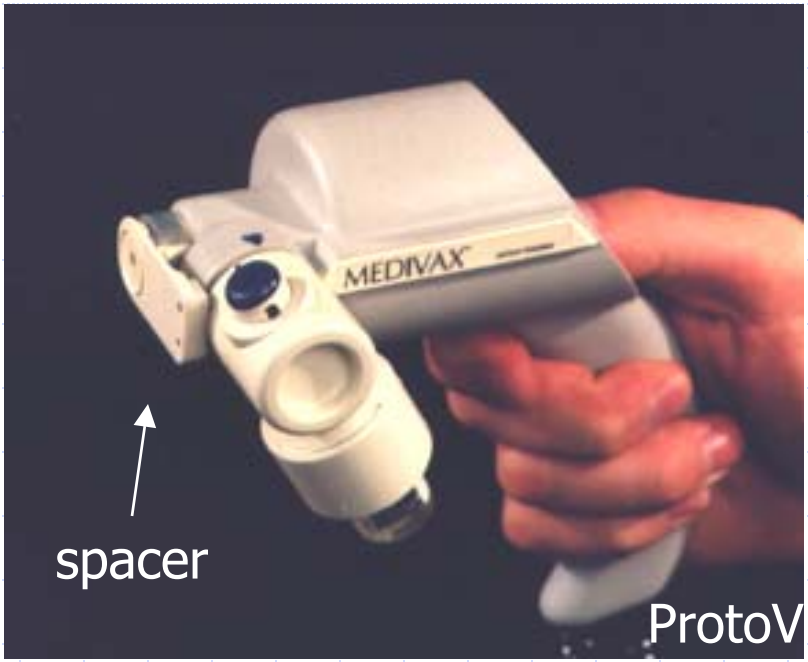
History of Jet Injector Development at PATH

- 16 years of in-house design and development experience (MEDiVAX, N-Ject)
- Evaluation and testing of numerous jet injectors
- Portfolio of patents and know-how (needle-free) – US government subject invention
- Collaboration with Felton International

MEDiVAX Design: 1988-1997



- Development funded by USAID under HealthTech
- Collaboration with Vitajet
- Low workload injector – routine immunization
- Air powered system (foot pump) – novel design
- Incorporated "spacer" to prevent cross contamination
- Field assessment 1989-1995
- Bench and animal studies demonstrated that cross contamination occurs

MEDiVAX Field Assessment


Bolivia -1989


Russia -1995


Indonesia -1992

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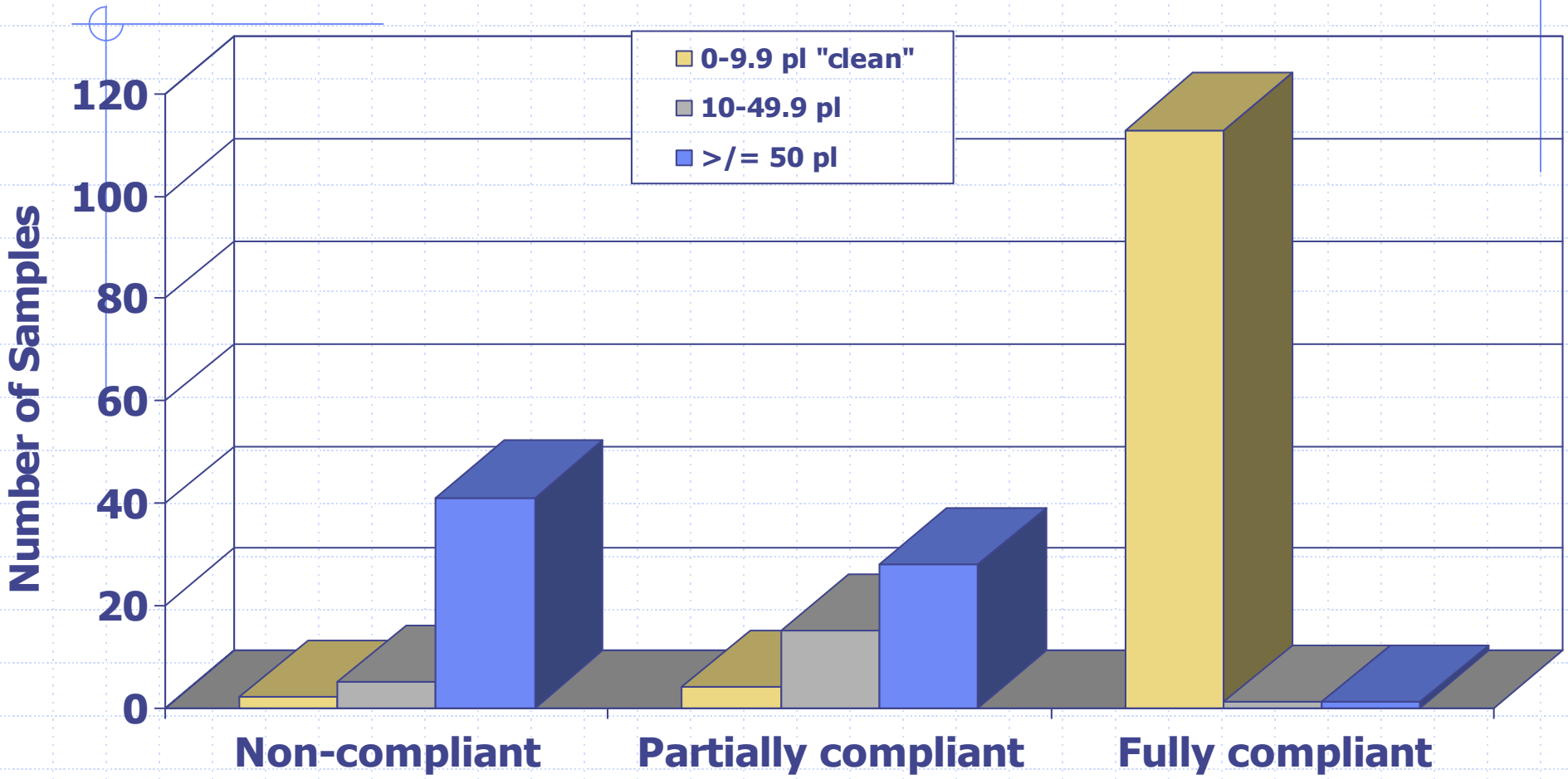
MEDiVAX Contamination Testing (1997 PHLS)



Hoffman PN, Abuknesha RA, Andrews NJ, Samuel D, Lloyd JS. A model to assess the infection potential of jet injectors used in mass immunisation. Vaccine 19 (2001) 4020–4027

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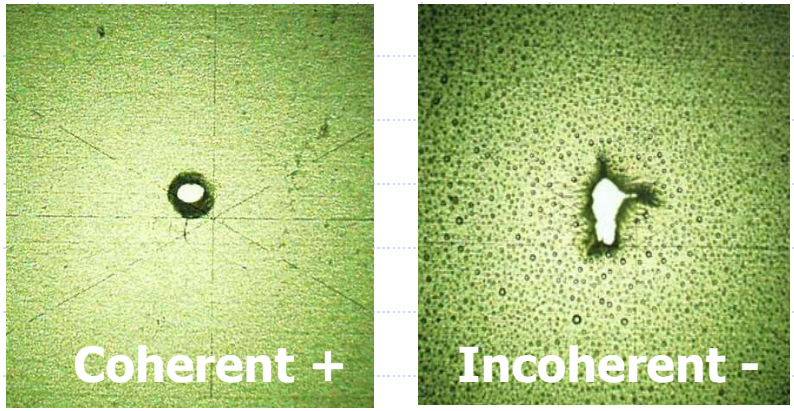
N-Ject Design: 1997-1999

- Use of disposable ampules
- Pre-fill or fill on site
- "Filling station" design developed
- High life cycle nitrogen spring (handpiece)
- Project shelved due to the following challenges:
  - Performance issues – molded ampule
  - Vaccine manufacturer prefill
  - Fill on site – sterile transfer
  - Necessary development funds not available

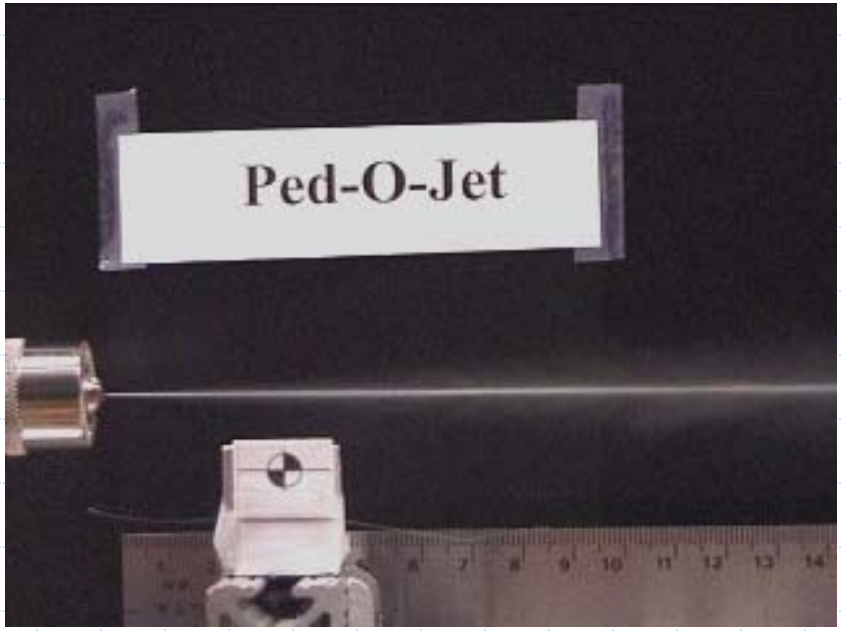
Developmental Tests: 1988-2003

- Evaluation of design iterations
- Baseline/predicate device comparison
  - Dosage
  - Stream Focus
  - Penetration
  - Force
  - Stream Coherence (video/photography)
  - Contamination

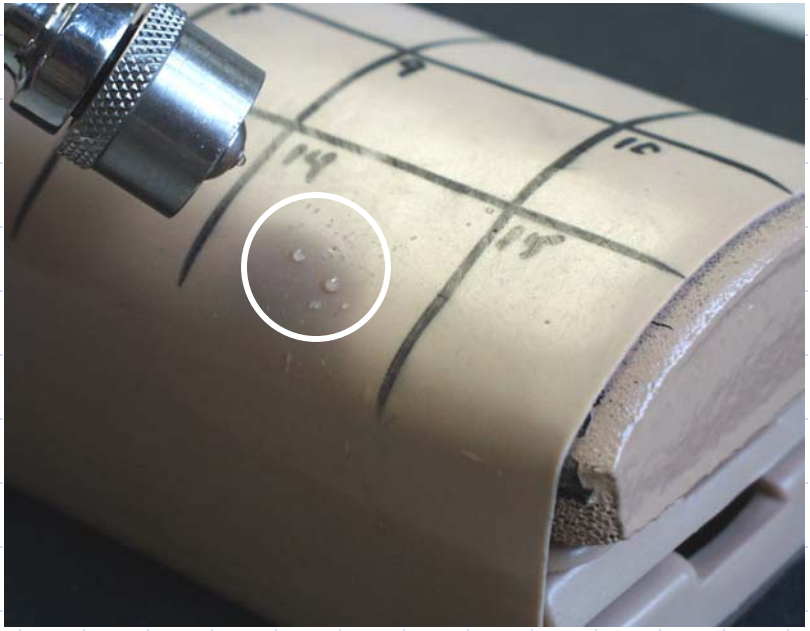


Stream focus – optical comparator image

Development Tests (cont.)

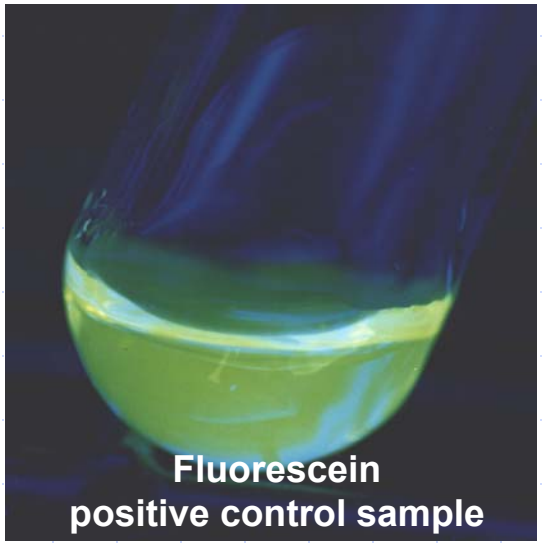


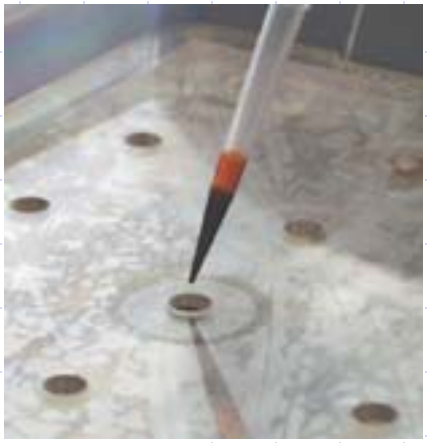
Stream Coherence – video



Penetration – tissue simulant

PATH Fluorescein Bench Test





Injection "wells"

- Sensitivity: 2.5 pL per 0.5 cc dose
- Models "ballistic" contamination event
- Bench test intended to inform designers and engineers during product development
- "Worst case" scenario — does not accurately replicate tissue response — represents maximum challenge

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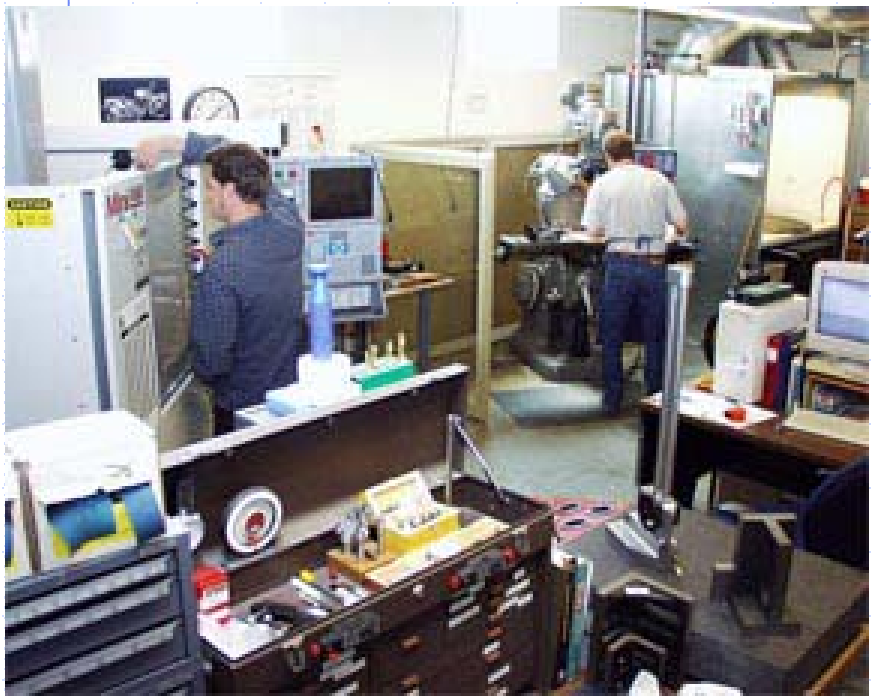
PATH Product Development Shop

- Tremendous growth over the past 15+ years
- Extensive in-house product development capabilities (injection molding, machining, testing, environmental)



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PATH – Felton International Collaboration

- Project Goals:
  - Design and development of a low cost, mass immunization campaign injector suitable for developing country use
  - Reversal/modification of current WHO policy to allow for use of the mass immunization campaign injector
  - Re-introduction of the campaign injector into developing world

History of Collaboration — PATH and Felton International: 1998-2003

First Russian injectors evaluated – Alan Felton	1998
BI-3M tested and evaluated	1998 - 2001
Mass campaign jet injector specifications drafted w/WHO (BI-100)	1999 - 2000
Protector cap iterations and testing (fluorescein test development)	1998 - 2003
USFDA 510(k) clearance (BI-3M)	2001
Initial BI-100 prototypes	2001
Senegal field evaluation	2002
Final design and verification testing	2003

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PATH project work funded by USAID under HealthTech

Felton International Campaign Injector

Original BI-3M

- Protector cap
- Variable dose/pressure
- Weight and ergonomics difficult for users (handpiece and foot pedal)
- Over 100 million injections delivered by BI-3 injectors in the former Soviet Union

BI-100a

- Smaller/lighter than original BI-3M
- Fixed 0.5 cc dose
- SC or IM delivery
- Simplified foot pedal
- Single pressure setting
- Redesigned protector cap

BI-100b

- Ergonomic design changes
- Universal vial adapter
- Modified trigger location
- User input required to verify design approach

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DESIGN DEVELOPMENT 1998-2002

Senegal Field Evaluation

Protector Cap Injector: September 2002

- Purpose: Human factors evaluation of prototype design
- Focus group sessions/training
- 3 Senegal sites:
  - St. Louis
  - Richard Toll
  - Podor

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Senegal Field Sites

St. Louis

Richard Toll

Podor

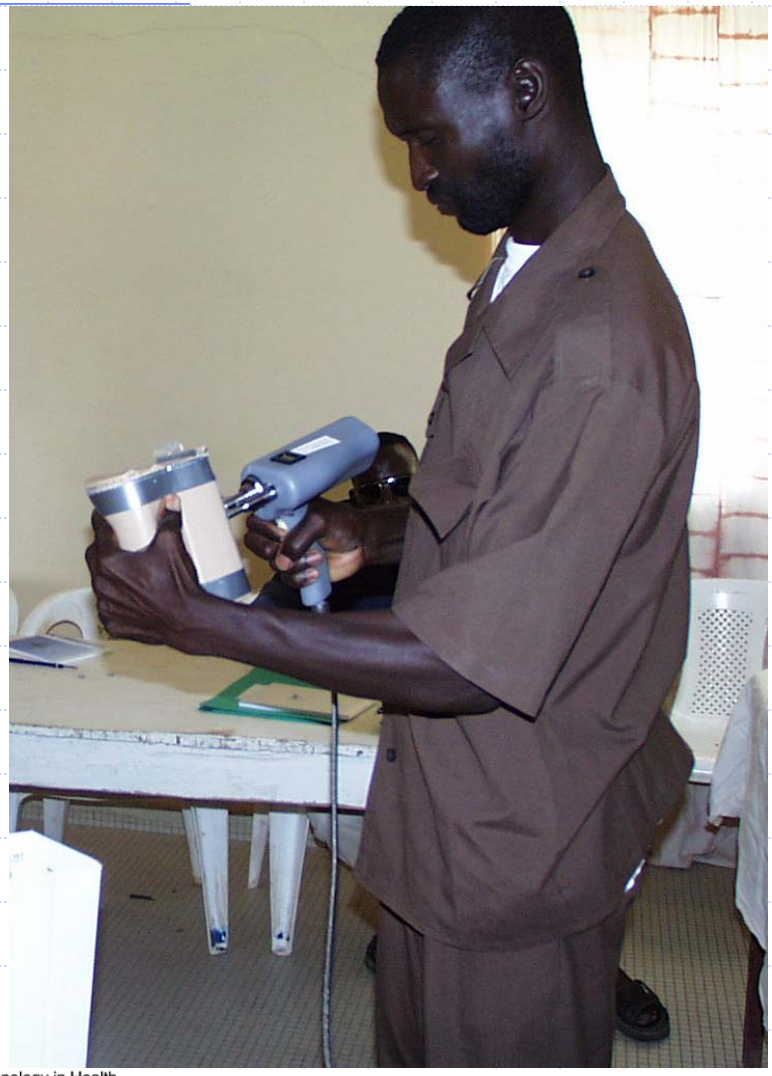
Device Training (1)

Inspecting the protector caps

Protector cap placement

Device Training (2)

Injection practice with tissue simulant



Focus Group Discussions

Richard Toll User Evaluation

Podor User Evaluation

Human Factors

Hand piece difficult to hold

Operating the injectors barefoot

Dirt in the foot pedal

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Human Factors
Device and Cap Handling

Simulated injection and loading the protector caps

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Cap Handling

Protector cap and package management – challenges

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Waste Management

Outcomes from Senegal Field Evaluation

- Human factors input received prompted redesign of handpiece and footpedal – led to the new "torch" design
- Training will be critical to proper usage and acceptance
- Must address logistical issues such as waste management and field sterilization

New "Torch" Design – Jet Injector for Mass Immunization

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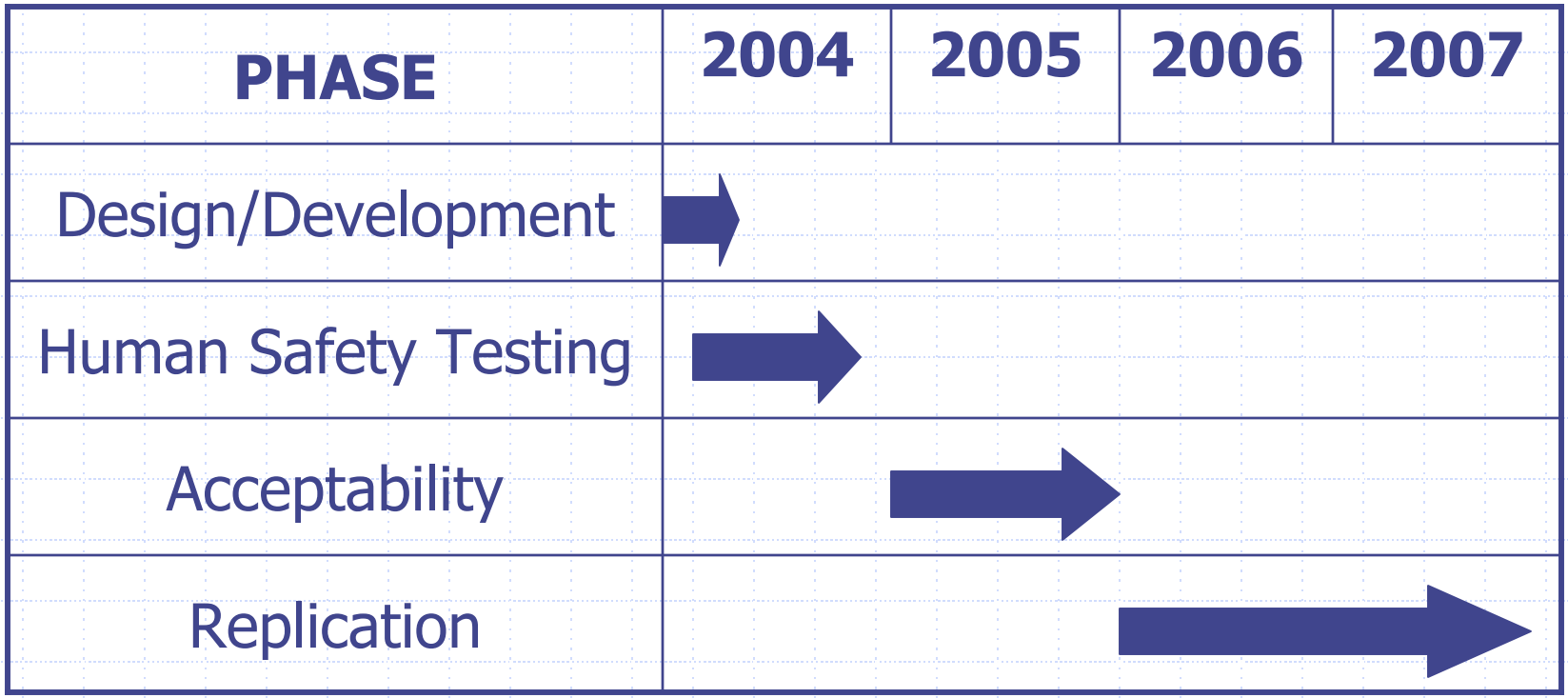
Jet Injector for Mass Immunization – PATH Strategy



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Thank You