What's New in Immunizations?

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Children's Minnesota

Washington Vaccine Update
10.27.17

National Foundation for Infectious Diseases®

Disclosures

- No financial conflicts to disclose
- Some content from NFID, Clinical Vaccinology Course, used with permission. Thanks to Phyllis Arthur, William Schaffner
- Vaccine research phases from CDC.gov

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Successful completion of this continuing education activity includes the following:

- Attend the entire conference
- Complete an online evaluation at http://www.surveygizmo.com/s3/3840875/WA-Vaccine-Update-Learner-Evaluation
- Complete an online certificate request at the link above

If you have any questions about this CE activity, contact Margaret Stahl at seattle@cardeaserivces.org or (206) 447-9538

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Acknowledgment

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Learning Objectives

By the end of this session, you should be able to:

1. Describe recent changes in HPV vaccine recommendations
2. List some expected changes in vaccine recommendations in the near future

Topics

- Describe the journey of vaccines and learn how vaccines are approved
- Describe most recent ACIP recommendations for adult and childhood/adolescent immunization
- Review what is in the pipeline for vaccine research and development

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About NFID

Non-profit 501(c)(3) organization dedicated to educating the public and healthcare professionals about causes, treatment, and prevention of infectious diseases across the lifespan

- Reaches consumers, health professionals, and media through:
  - Coalition-building activities
  - Public and professional educational program
  - Scientific meetings, research, and training
- Longstanding partnerships to facilitate rapid program initiation and increase programming impact
- Flexible and nimble organization

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The Vaccine Journey

Research

Pre-Clinical Trials

Clinical Trials

Phase I: Animal testing

Phase II: Human Immune response

Phase III: Compares to other vaccines adverse events

Phase IV: Post-licensure tracking

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FDA Licensing

-product

-manufacturing site

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-product

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ACIP

Makes recommendations for practice implementation

~MMWR

~AAP

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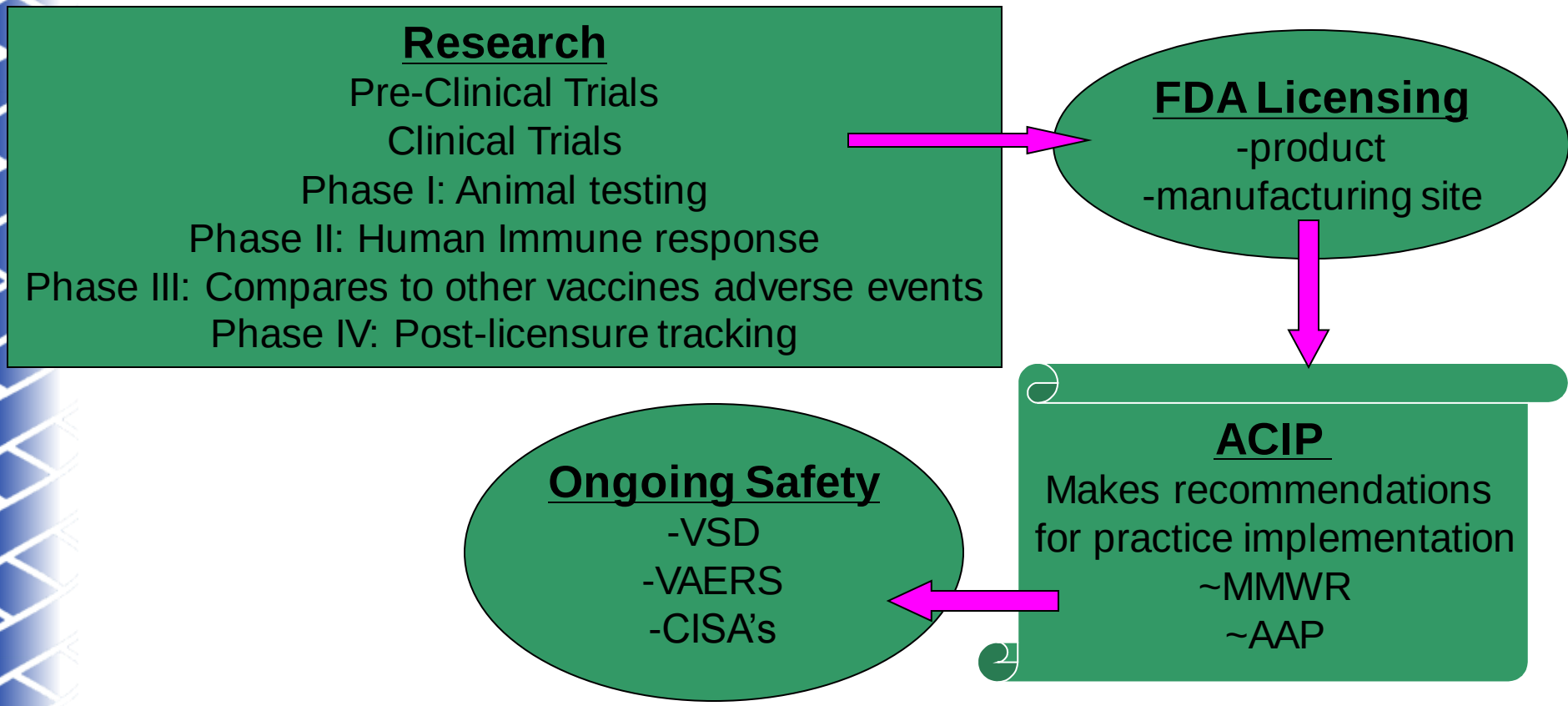
The Vaccine Journey



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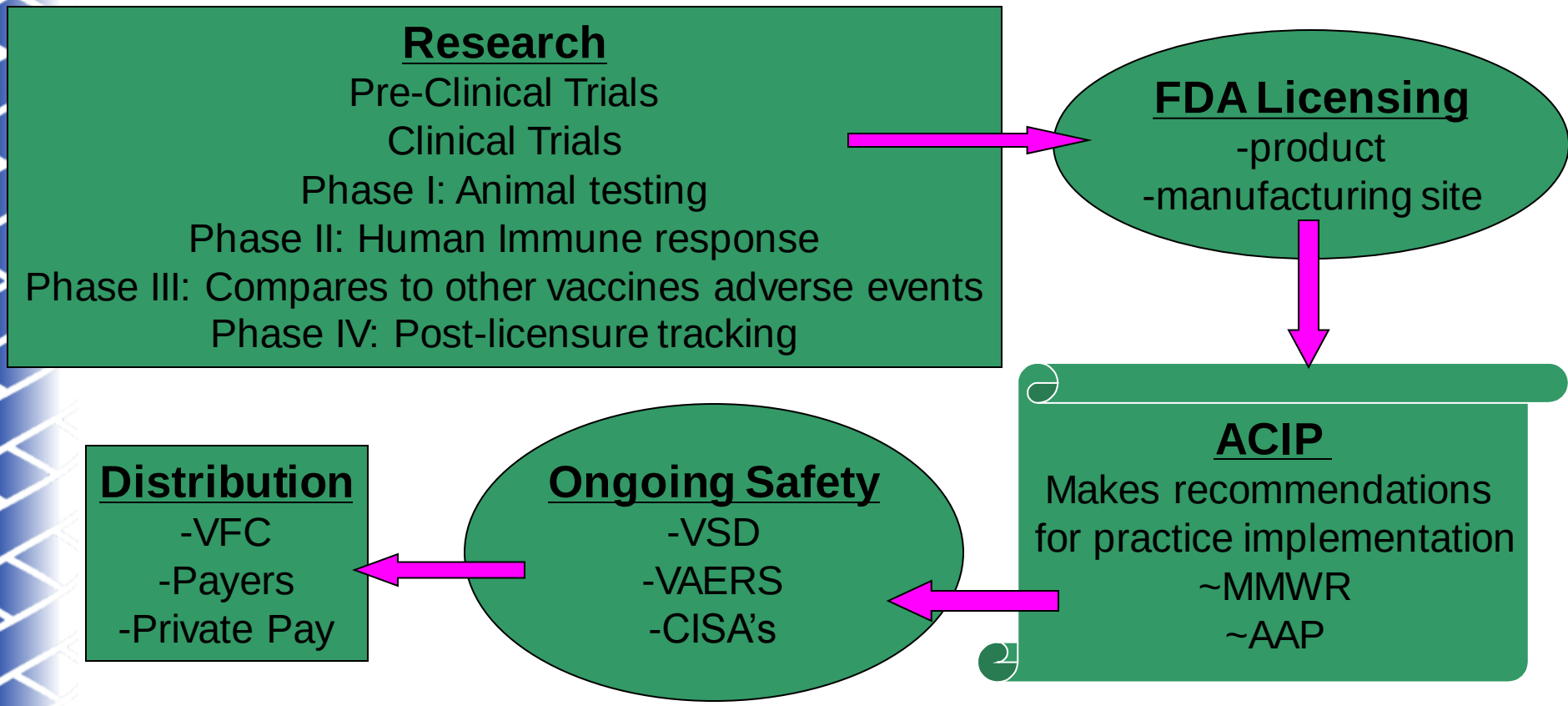
The Vaccine Journey



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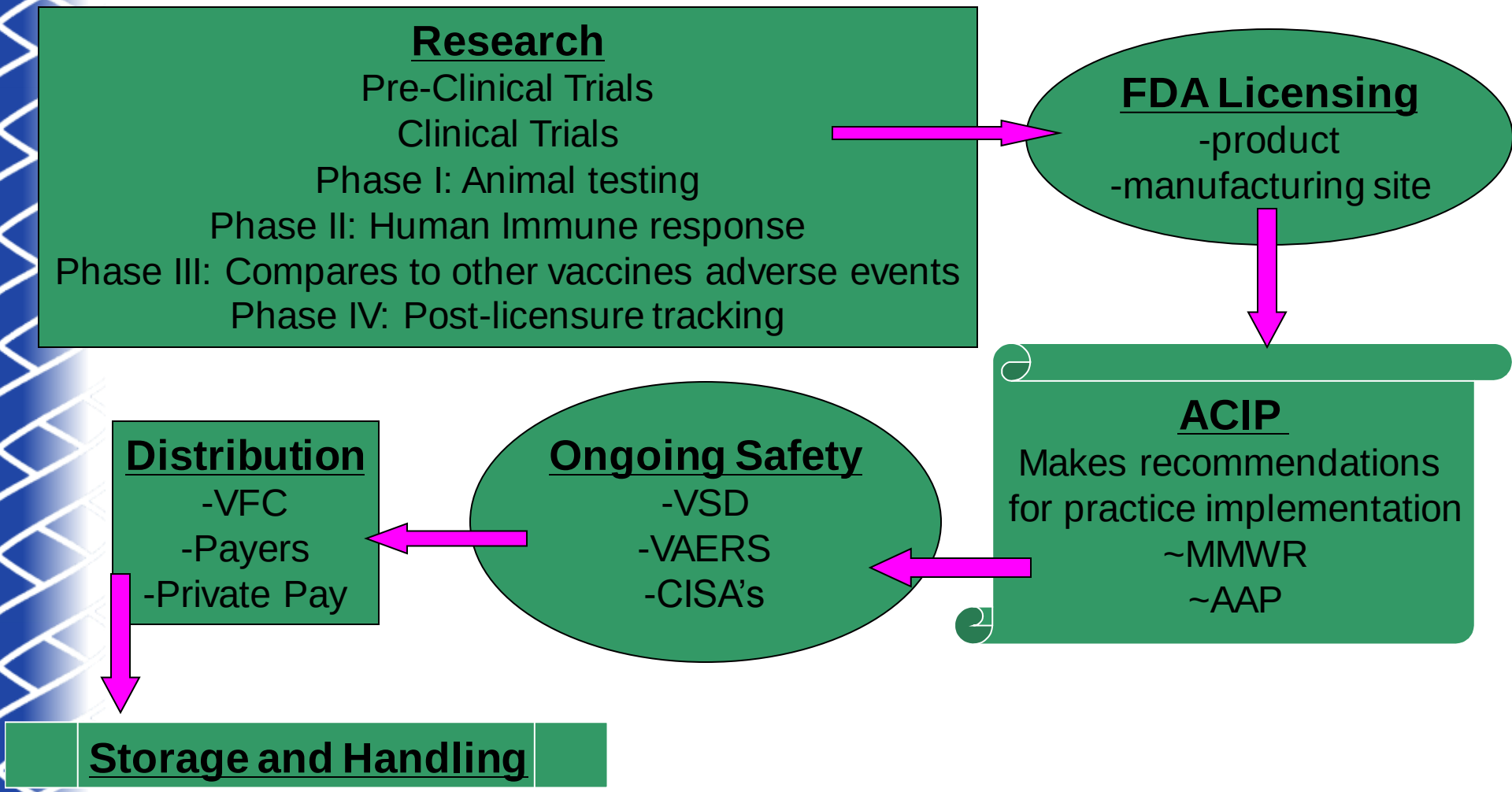
The Vaccine Journey



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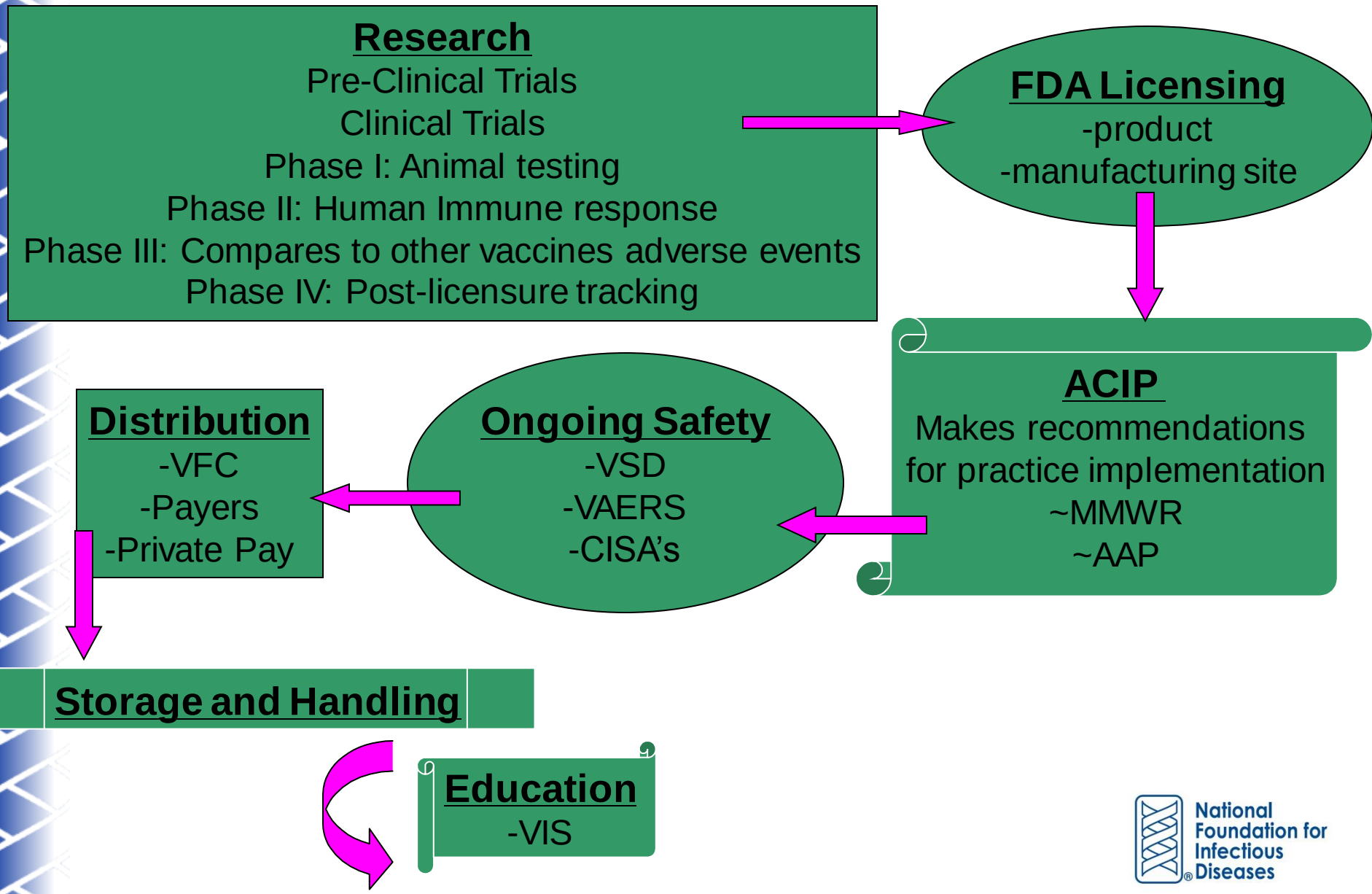
The Vaccine Journey



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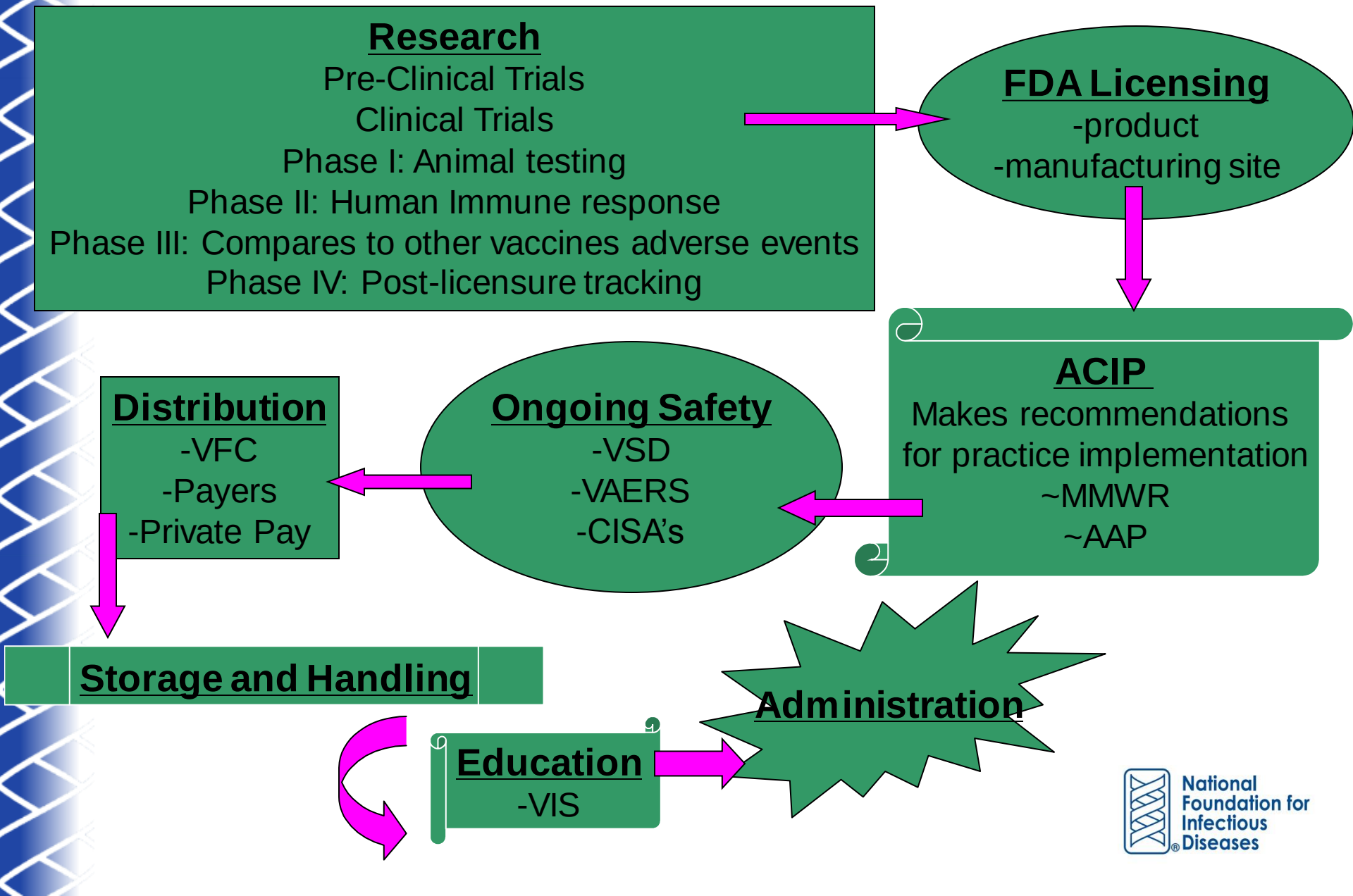
The Vaccine Journey



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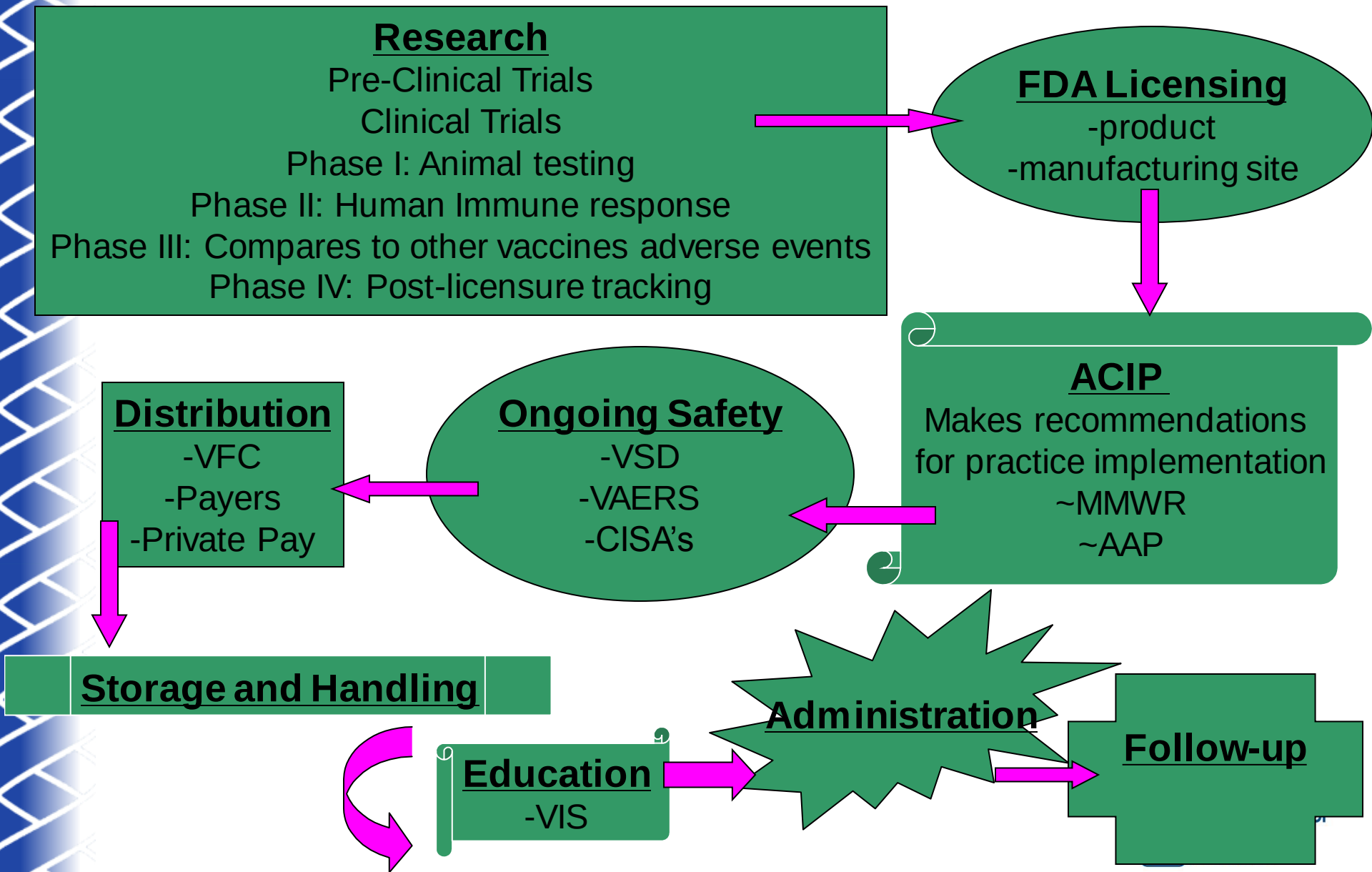
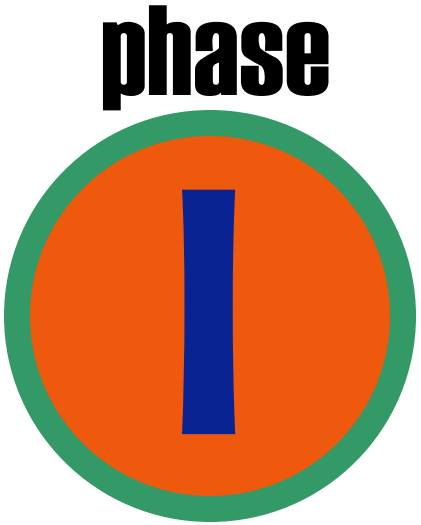
The Vaccine Journey



Four Phases Of Clinical Trials On People: Phase I Involves Animal Testing

- After years of research, a vaccine that's been proven safe on animals goes through four phases of trials on people.
- In Phase I, anywhere from 20 to 100 volunteers receive the vaccine.
- The first phase is limited to just a few people, because scientists are triple-checking for safety, looking for serious side effects.



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Phase II Trials Are Long And Complicated.

- Hundreds of volunteers take part in Phase II trials.
- These trials might take a few months, or they might last for years.
- Safety, safety, safety—that's still being studied in Phase II.
- Phase II tests also explore how the human immune system responds to the vaccine.

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Phase II Also Finds The Precise Dose.

- Now the vaccine is fine-tuned. Phase II trials set (1) the most effective use of the vaccine, (2) the best dose for effectiveness and safety, and (3) the right number of doses.
- Adverse reactions are recorded. *Local reactions* include redness and swelling where the vaccine is given. General bodily reactions, such as fever or muscle aches, are also tracked.

- Some Phase II volunteers will get placebo or another already licensed vaccine to compare outcomes.

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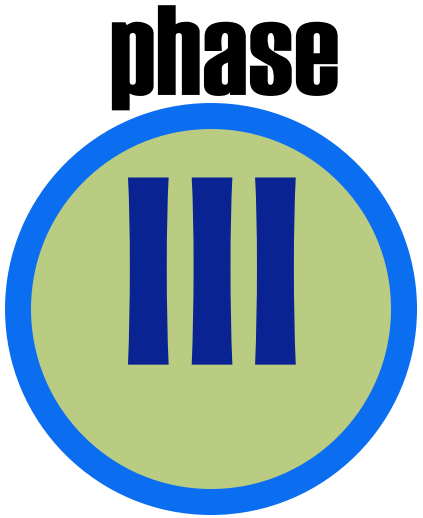
Phase III
(The Longest One Of All)



- Phase III trials may last several years. A few hundred to tens of thousands volunteers may be involved.
- Some volunteers receive another already-licensed vaccine instead of the vaccine under study.
- That way, researchers can compare one vaccine to another for adverse effects—anything from a sore arm to a serious reaction.
- If everything about the proposed vaccine checks out for safety and effectiveness in Phase III, the manufacturer applies for a license from the Food and Drug Administration (FDA).

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One License Won't Do—
There Have To Be Two.

- During the application phase, the FDA reviews everything: clinical trial results, product labeling, the manufacturing plant itself, and the manufacturing protocols.

- A biologic license is the license the FDA gives for the vaccine itself AND for the manufacturing plant where the vaccine is made.

Advisory Committee on Immunization Practices (ACIP)

- 15 members
- 3 meetings/year
- 36 liaison representatives from professional/academic societies
- 8 ex-officio members from federal agencies
- Media are present
- Public comment at each meeting
- Meeting agenda, transcripts, slides available at: www.cdc.gov

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Phase IV Tracks Vaccines After Licensing.

- A license can be recommended or refused. This decision is made after an FDA team of specialists (microbiologists, chemists, biostatisticians, and medical officers) assess the safety data from the vaccine trials.

- If a license is issued, post-licensure monitoring takes place.
- Monitoring is the continual tracking of tens of thousands of people who have been immunized with the vaccine under study.
- Post-licensure monitoring gives valuable information about the vaccine's long-term safety and effectiveness.

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Vaccine Adverse Event Reporting System (VAERS)

- Sometimes, rare side effects and delayed reactions don't show up in clinical trials.
- So, once a vaccine is released to the public, data on effects and reactions are gathered continually.
- To make the gathering of information about potential side effects as complete as possible, the CDC and the FDA started a national system called the Vaccine Adverse Event Reporting System (VAERS) in 1990.

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Frontiers of Vaccines Beyond Preventing Diseases in Children

New Populations

- Adults
- Pregnant women
- Pre-surgery prevention

New technologies

- Adjuvants
- Platforms using new cell lines and approaches
- Gene editing and sequencing

Emerging Diseases

- Ebola
- Zika
- Outbreak response

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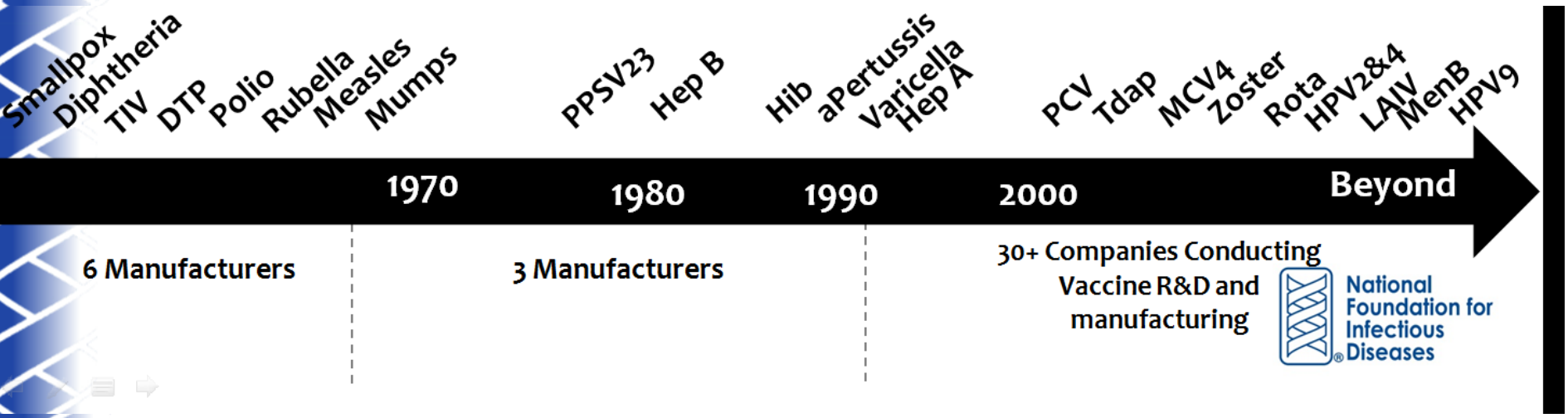
More Manufacturers than Ever



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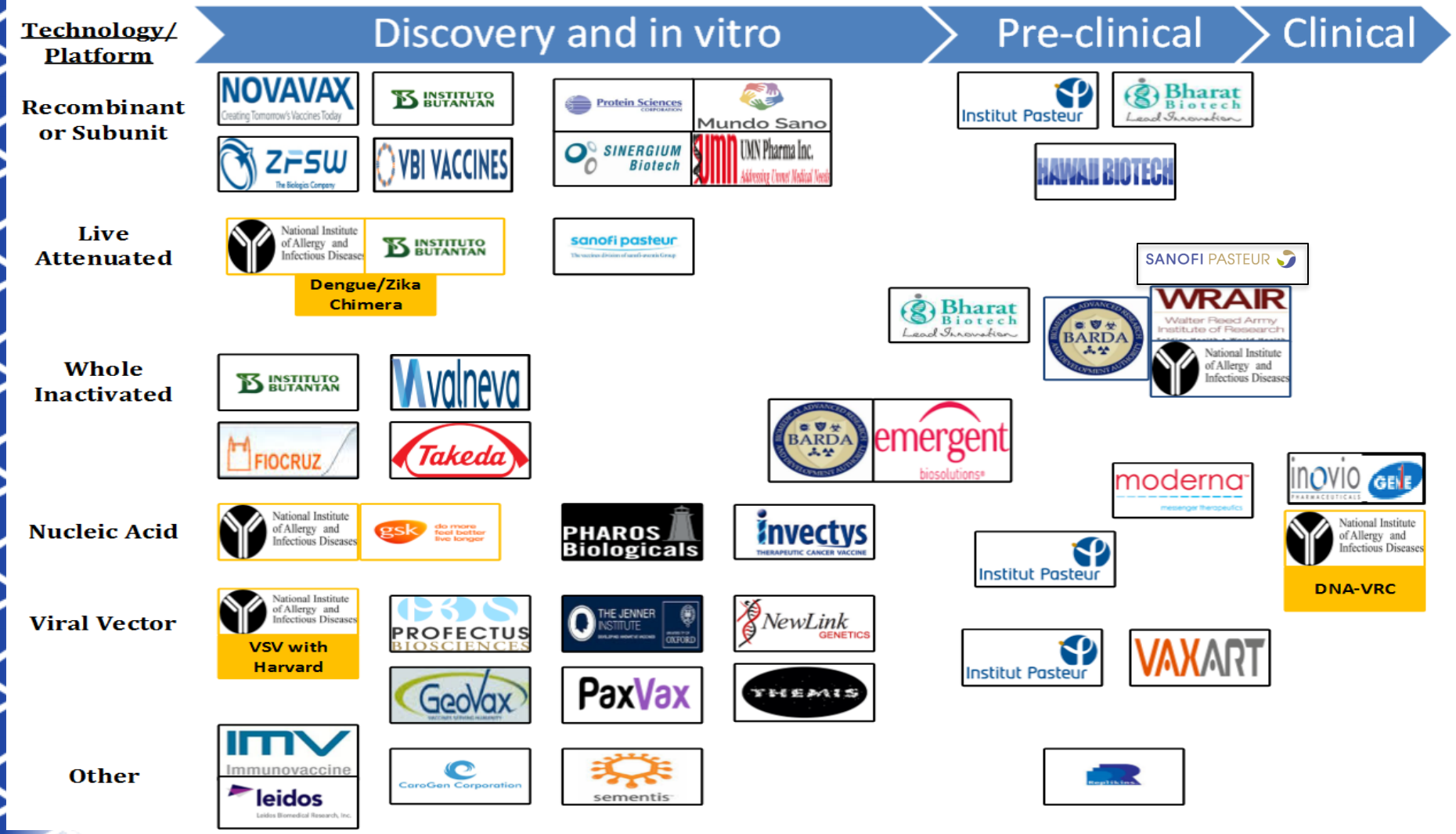
Zika Vaccine Landscape 9/12/16



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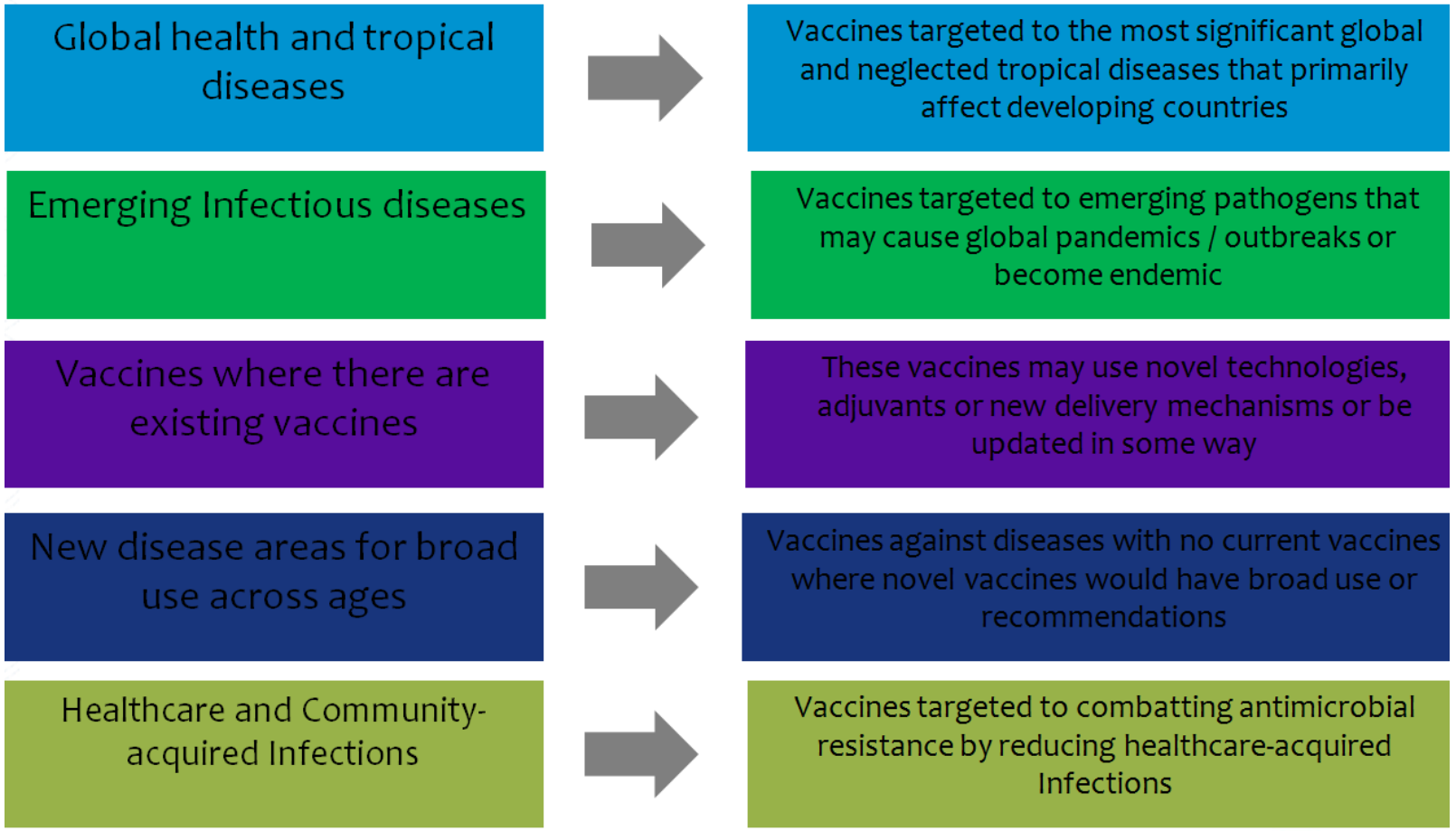
Areas of New Vaccine Development



Vaccines on the Horizon

Data Sources: BioMedTracker, FDA website, clinicaltrials.gov, company websites through October 2016

Vaccine Areas of Research	Specific Vaccines in Development
Global & Tropical Diseases	HIV, TB, Malaria, Dengue, Yellow Fever, Typhoid Fever, Cholera, Leishmaniasis
Emerging Infectious Diseases	Ebola, Zika, MERS/SARS, West Nile, Marburg/Plague, Smallpox, Pan Flu, Chikungunya
New Vaccines where there are Existing	Flu, Herpes Zoster, Hib, Pneumococcal, Hepatitis B, Meningococcal, HPV, Pertussis
New Vaccines for diseases with none	RSV, CMV, E Coli, Hepatitis C, Group B Strep, Norovirus, Herpes Simplex Virus
New Vaccines against Antimicrobial Resistance	Staph Aureus, Candida, Strep Pneumo, E Coli, Salmonella, Shigella, Mycobacterium TB, C diff, Group B Strep, Pseudomonas Aeurigenosa

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ACIP Recent Hot Topics

June 21-22, 2017 ACIP Agenda

One VOTE:

- Influenza vaccine. Recommendations the same—all persons 6 months of age or over receive injectable influenza vaccine. No LAIV approved.

February 22-23, 2017 ACIP Agenda

One VOTE:

- Hepatitis B vaccine in infants born to Hepatitis B positive mothers, updated recommendations and Vaccines for Children (VFC) vote

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VOTE: Hepatitis B revaccination for infants born to HBV+ Mothers

- Language will allow lab testing after initial 3 dose series and if seropositive, no further vaccines
- If seronegative, may do one additional dose and retest
- Language remains that allows for choosing to just repeat the 3 dose series without lab testing after the first dose followed by lab testing after the 6th dose
- If Anti-HBs is $\geq$ 10 is protected, no further vaccination or testing.
- If Anti-HBs is $\leq$ 10 is a non-responder, no further vaccination or testing.

February and June 2017 ACIP

DISCUSSION ONLY TOPICS:

- Influenza
- Adult Immunization
- Herpes Zoster Vaccines
- Meningococcal Vaccines
- Global Immunization Update
  - Polio eradication
  - Dengue, Zika, Yellow Fever
- Vaccination Errors
- Mumps Disease and Vaccine

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Herpes Zoster Vaccines

- Epidemiology of herpes zoster (HZ) reviewed (1 million cases in US annually, lifetime risk 1:3
- Current vaccine (Zostavax®) efficacy 51% HZ, 67% post-herpetic neuralgia
- Uptake at ~28% adults 60 years and over

- 2 new vaccines for the prevention of HZ are being evaluated and not yet approved by FDA; both in phase 3 efficacy trials in persons 18 years and older:
  - HZ/su (GSK) glycoprotein E + adjuvant 2 dose series
  - V212 (Merck) inactivated formulation of Zostavax®

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Zoster Vaccine(s)

Merck	GSK
Zostavax® (ZVL)	Shingrix™ (HZ/su)
Attenuated Live chickenpox (x14)	Glycoprotein E + adjuvant
1 dose	2 doses, a month apart
	More local reactions
Adults ≥ 60	Adults ≥ 50
Efficacy vs shingles 51%	Efficacy vs shingles 92%
Efficacy vs PHN 65%	Protection maintained over 4 yrs
Protection wanes over 7-10 yrs	

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Herpes Zoster Vaccine Policy Questions

- Should ACIP recommend HZ/su immunocompetent adults? (Category A or B?)
- At what age should HZ/su recommendation start?
- Should ACIP recommend a preference for HZ/su over ZVL?
- Should ACIP recommend persons previously vaccinated with ZVL receive HZ/su?

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Vaccination Errors

Vaccine Safety Office Tom Shimabukuro, MD, Beth Hibbs, RN

- Great presentation. Lots of committee comments, questions
- VAERS in 2000-2013 311,185 reports, 7% are error reports (21,843)
- Main error is inappropriate schedule (27%), storage and dispensing (23%) and wrong vaccine (15%) 2/3rds of errors
- Top 3 vaccines with errors are often sound alikes Varivax/Zostavax, Dtap/Tdap, IIV age indication issues, Pneumo conjugate/pneumo poly, HepA/Hep B.
- 75% of vaccination errors reports to VAERS did not document adverse health events (AE)
- Of the 25% error reports that did have AE they were similar to non-error related reports. 92% are non serious reports
- Case studies: rotavirus injected, insulin instead of influenza, injecting diluent

Strategies for reducing vaccination errors

- Education and training on the schedule
- Training on administration techniques
- Monitor vaccine storage temps
- Pay attention to expiration dates
- Engineer differentiation between sound alike names/acronyms
- Screening for contraindications standardized
- Engineer interventions
- Bar coding for box and product to match

Mumps Epidemiology

- Mumps vaccine has reduced disease by 99%
- Mumps outbreaks persist 2006, 2010, 2016 (nearly 6000 cases)
- Most are in fully vaccinated college students
- If vaccine immunity is waning, no older vaccinated cases
- 2 dose schedule may be sufficient for general population
- 3 doses commonly used in outbreaks
- Benefit of 3rd dose in general population needs assessing

Mumps Disease and Vaccine Questions for the Workgroup

- Why do we see mumps primarily in a tight age-range of teens and young adults? (19-23 years median in 16 outbreaks).
- When the outbreaks occur, they are largely on college campuses where there are close living situations, but we don't similarly see mumps outbreaks in military recruits. Why not?
- If we are seeing waning immunity of the vaccine how does that explain specific geographic outbreaks and no cases in older adults?
- Are certain populations at higher risk for mumps disease compared to others?
- Are there proper vaccine storage and handling concerns in certain areas?
- Has there been a shift in mumps genotypes in the US compared to what is in the vaccine?
- Should a third dose of mumps containing vaccine be used in an outbreak setting only or is there evidence to support a 3rd dose as a more broad routine recommendation.

Vaccine Adverse Event Reporting System (VAERS) 2.0

- VAERS 2.0 consists of two major initiatives
  - A new VAERS form with revised data elements
    - VAERS 2.0 reporting form
  - An updated processes for submitting VAERS reports
    - Option 1: updated online reporting tool
    - Option 2: writable PDF form combined with electronic document upload capability

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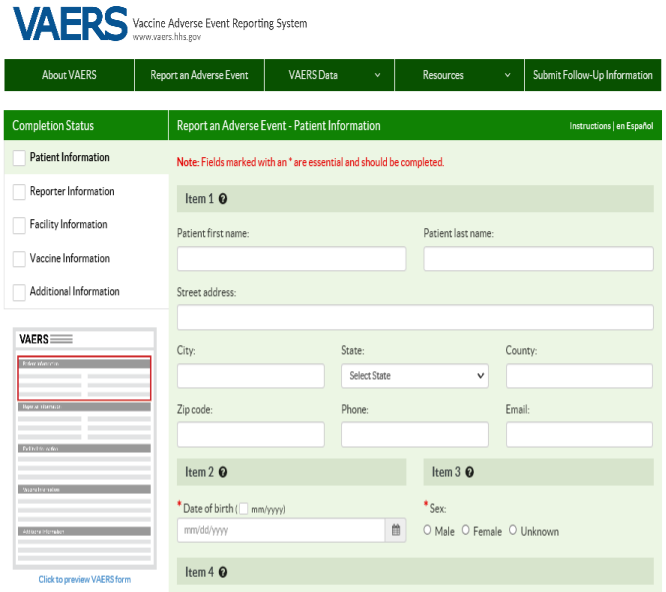
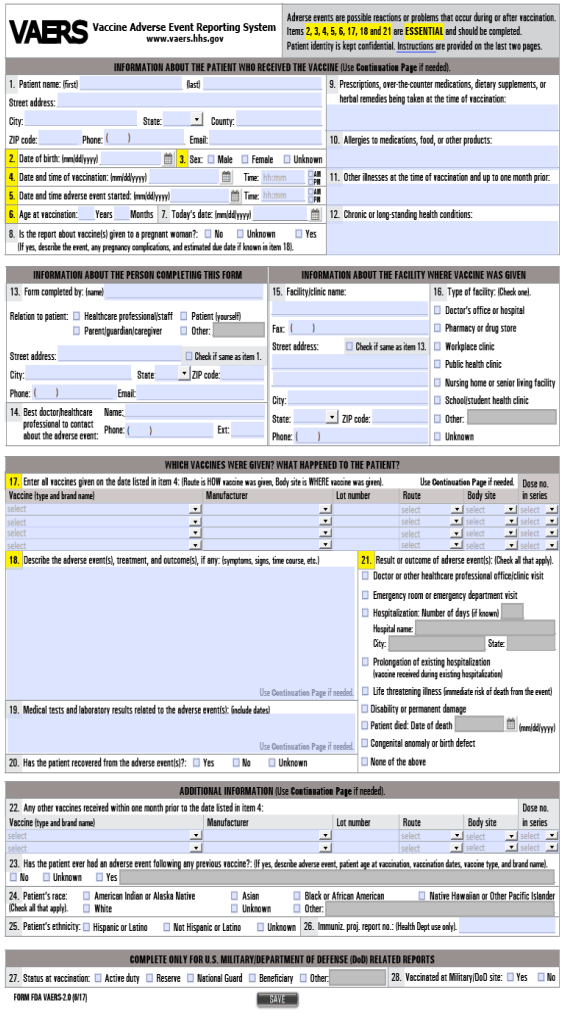
Partial Screen Shot of VAERS 2.0 Online Reporting Tool (Direct Online Reporting)



VAERS 2.0 Form (Writable, Savable, and Uploadable to VAERS Website)



- "Essential" items (high value data elements) are highlighted with asterisks in the online reporting tool and with yellow boxes in the writable PDF form

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The Perfect Vaccine—We can dream!

- Single dose
- Oral
- Omnivalent
- Neonatal
- 100% effective
- No adverse events
- Lifelong immunity
- Loved by providers, nurses, parents and the media
- Easy to pronounce and talk about

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