Immunize Weekly Summary: May 7, 2026

- Update on New Vaccines in the Pipeline
- Announcements

Update on New Vaccines in the Pipeline – Phyllis Arthur, Executive Vice President & Chief of Global Health at Biotechnology Innovation Organization (BIO)

Phyllis Arthur gave an update about new vaccines and monoclonal antibodies in the infectious disease prevention pipeline.

VIEW SLIDES

Infectious Disease Prevention Pipeline – Phyllis Arthur

The data presented in this webinar was current as of April 8, 2026. It was sourced primarily through Citeline Biomedtracker and considered vaccines and monoclonal antibodies in any phase of development, to be used for preventative purposes, and with the intention of being approved in the United States.

Pipeline Overview of the Phases of Development

In 2026, there are 308 total products in the pipeline; in 2025, there were 560 products total. The decrease reflects methodological changes as well as pipeline attrition, not solely product exits. The current 2026 analysis: Excludes polyclonal antibodies, includes only preventive (not therapeutic) vaccines, covers products in U.S. development only, not global pipelines

  - The changes that companies might be making in investment in their R&D portfolios based on the current policy environment and issues with the FDA may not show up until later in 2026 or in 2027.
- More than half of all vaccines currently in the pipeline are in preclinical development.
- COVID accounts for 50% of the pipeline, including monoclonal antibodies. There are technologies still being researched for COVID to make next generation vaccines. The next largest percentages are:
  - Flu — 28% of vaccine in the pipeline.
  - RSV — 9% of monoclonal antibodies and vaccines in the pipeline.
- It's important to have enough products in the pipeline to see at least one get through to have the opportunity for FDA approval.

Vaccines

- The expectation is that some of the COVID products in the pipeline will drop off but some new products, being developed from new technologies, will make it to market

with government and investor funding, which will afford more options for COVID prevention.

- Moderna's influenza vaccine, an mRNA vaccine, has been submitted to the FDA and globally for review by regulatory agencies as a vaccine just for flu and in combination with COVID.
    - Their combination influenza/COVID vaccine was approved by the European Medicine Agency (EMA) and approval in other countries is expected as well.
- Several other products are expected to be submitted for approval in the United States in the next 4 to 6 months, which could bring products to the market next year.

Vaccines in Late-Stage Development (Phase III)

Products at this stage are most likely to be submitted. Highlights from this list include:

- COVID-19: 4 products — several are COVID-flu combinations, some using new technology (e.g., pill form)
- Influenza: 4 products — 3 seasonal, 1 pandemic
- Pneumococcal: 3 products — all currently seeking adult indication; there is potential for pediatric indications
- Norovirus: 2 products — 1 is an mRNA vaccine, 1 product did not meet efficacy goal in infants and is shifting to adults
- *Clostridium difficile* (*C. diff.*): 2 products — there are promising studies ongoing in older adults
- Lyme disease: 1 product — it has received fast track designation from FDA and may be filed soon. It is for children ages 5+ and adults

Vaccines in Late-Stage Development (Phase II)

These products show promise to move to largest trials in Phase III. Highlights from this list include:

- Influenza: 10 products
- COVID-19: 9 products
- RSV: 4 products
- Pneumococcal: 2 products with pediatric indications
- Shingles: 2 products — 1 is in a comparison trial with Shingrix, 1 is an mRNA vaccine
- Viral, Other (Hantavirus): 1 product which uses needle-free IM delivery and may get increased attention or investment based on news of current outbreak on cruise ship

Vaccines in Early-Stage Development (Preclinical and Phase I)

Most vaccines in Phase I are top pathogens that are usually targeted. Missing are gonorrhea and some other STIs that don't seem to be able to get necessary research funding. Highlights from this list include:

- COVID-19: 66 products
- Influenza: 30 products
- RSV: 10 products
- Malaria: 7 products

- Norovirus: 7 products
- Zika Virus Disease: 6 products

Monoclonal Antibodies (mAbs) in Late-Stage Development (Phase II or III)
There is likely to be continued investment in these products as an adjunct to vaccination and a way to treat those who might have been exposed but are not yet sick, and those who are immunocompromised. The use of mAbs during COVID allowed for a new level of delivery that could make them a powerful tool for prevention and treatment. Highlights from this list include:

- COVID-19: 6 products — with 1 in Phase III
- Influenza: 2 products — 1 is in Phase II, 1 is in Phase III
- *Clostridium difficile* (*C. diff.*): 2 products, intended to prevent recurring *C. diff.*
- Staphylococcal: 1 product

Antibodies in Early-Stage Development (Preclinical and Stage 1)
The use of mAbs for handling infectious diseases for those at highest risk or where the delivery of long-term immunity through vaccine has not been achieved is exciting. Highlights from this list include:

- COVID-19: 5 products
- RSV: 5 products
- Influenza: 5 products
- Pertussis: 1 product
- Chickenpox and Shingles: 1 product

New Indications of Importance

- RSV for adults expanded for ages 18 to 49 at high risk, in March 2026
- Pneumococcal vaccine for children

QUESTIONS & ANSWERS
Q: You pointed out the reduction in number of products in 2026 and the current environment. With these products in Phase III right now, are you anticipating challenges in the approval process? What's the current environment with regards to R&D as far as manufacturers are concerned? Are there alternatives to regulatory approval pathways that are outside the United States? What's the big picture?
Phyllis Arthur (BIO): Companies are watching the FDA very closely. As we talk to companies, those working more with adult vaccines seem to be having decent interactions with their reviewers at the FDA. I think that companies are nervous about what they saw as the sudden changes of mind around how studies were conducted when they had agreement not just from FDA personnel from before this administration, but [also] from FDA personnel in this current administration. I think companies are nervous. I think they are watching the space carefully and engaging with the FDA as much as they can in verifying: this is what we talked about, this is how the study is done, these are the endpoints, this is how it's going, with

the hope — particularly those in Phase III — that there are no changes of opinion. I think that's one of the most interesting things: the reviewers have a lot of history and skill in reviewing these products. I think the thing that makes people nervous is [any] second-guessing later. I think companies are trying to plan for it but know that they can't exactly plan for it. We were very happy to see the RSV indication happen without a hitch. We have a couple of litmus tests coming up: the new indication for the pneumococcal vaccine, what happens with Moderna's flu vaccine, how the filing goes — that will be our test, because we are now operating in an FDA that doesn't have the same personnel either. Dr. Prasad had an influence; he's not there since April 30th. This will be a wait-and-watch period where we will see whether the FDA has taken on a little more of its classic role, or whether we still have some of the weighing in from more of a political perspective that we had earlier in the year.

Q: The wait and hold part must be difficult, because I imagine the research and the continuation of Phase II trials is going to progress. It's not like a company can say, "Let's pause the clinical trial," or "Let's pause the research." At some point, they're going to outpace where things are at FDA, if FDA is still on a wait and hold. What does that mean?

Phyllis Arthur (BIO): When you get to the end of your II B, your Phase II meetings, you sit down and you… but this happened for most of these companies under a totally different administration and a different FDA. So, some of these companies are just starting Phase III, so they're having these conversations where they're saying here's our plan, here's our design, here are our endpoints. Most people do their trials globally… here's the indication I am seeking and how I want to prove that I am going to get there. And they're taking those meetings now. It's hard when you're at the end of that trial, and you had agreement on everything, and you start to go in and show where the data is, and then you get someone who says, "I wish you had chosen a different endpoint," or "I wish you had chosen a different comparator vaccine." Those are things you cannot fix. I think this is a reaction to what happened with Moderna's vaccine — they need to give you the review and have that conversation — and how that ends up affecting whether you get that full indication or caveats in your label is the thing I don't think we've seen yet. So, I think we are watching these next few approvals, assuming they happen, and whether they happen straight, or whether they happen with some caveats around the indication itself or around the data.

Q: I know we can't really predict, but do we anticipate any monoclonal antibodies could potentially replace any vaccine doses in the schedule? Or would they be likely offered alongside as an option like RSV currently is, for instance, maybe protection for older adults during flu season, so flu monoclonal antibody?

Phyllis Arthur (BIO): I think there are very few mAbs that have the same ability to be offered in a vaccine-like way. Flu feels very similar, which is you're looking for a period of protection when the patient's most at risk, and so one could indeed say, "I will give a Flu mAb to healthcare workers, or to immunocompromised persons, either with a vaccine or apart from a vaccine." RSV is unique because we were having such a hard time making a vaccine for kids that worked, and the mAb strategy was uniquely well-positioned for protecting children in this very well-defined and well-understood window when they were at highest risk. So, I think flu is probably a good view there. It would be interesting to think

about whether COVID is a right view. I think it'll depend on what the next round of COVID maps looks like. What's weird about COVID is we keep saying it's seasonal, but is it? I struggle with the fact that it's not [appearing] seasonal. So, I still think of COVID as something you need a vaccine for. And for an immunocompromised person, you might need the double whammy of a vaccine and a monoclonal.
L.J Tan (Immunize/NAIIS): You can also imagine a good mAb would be good for someone at high risk for flu. You could give protection to someone that's high risk that would be almost right away, as opposed to waiting for an immune system to come up.
Phyllis Arthur (BIO): We have done both for my dad for that very reason. And the long-acting monoclonals changed the game.
L.J Tan (Immunize/NAIIS): Yeah, because they give you actual protection over a season, which is powerful.

Q: How are companies adapting to new regulatory guidance to reduce and eliminate use of animals in the preclinical development?
Phyllis Arthur (BIO): We're having a lot of conversations about this. Companies are working to do this as well. I think it depends on the product you're working on. You'll never be able to not use some animal models in most products. I think this is hard if you're working on products in diseases where animals are going to be the primary driver of your efficacy and safety trials, because you can't necessarily do the thirty thousand-person human trial that you want to do. So, research for your classic medical countermeasure product for emerging infectious diseases — while you're waiting for an outbreak to occur where you step in, like we did with Ebola, and use the product in humans — you are doing in non-human primates, you're doing some animal model. Companies are very committed to trying to find ways to do this, but we haven't quite landed on which technologies replace animal studies, particularly when everybody's worked so hard to figure out which animals most mirror human disease. We figured out ferrets, and we figured out pigs. I think this is work that everyone's committed to doing, but we're not at a point where it's a zero.
L.J Tan (Immunize/NAIIS): He's thinking about organoids.
Phyllis Arthur (BIO): This is a place where I am learning. There's a lot of interest in trying to move away from animal model work, particularly in the pre-clinical phase, the toxicology, farm talks, things like that. A lot of companies are committed to it, but you also must make sure the FDA agrees with you. Something you must do in partnership with the regulator, so when you walk in with the data, they recognize it as being the same caliber as what you would have done in animal models.
L.J Tan (Immunize/NAIIS): Organoids are three-dimensional tissue samples that people can use for organ testing, so you can basically test the toxicity of a vaccine or a drug on an organ.
Phyllis Arthur (BIO): A lot of companies are talking about organ on a chip, where you can kind of model these things if you want to make sure you don't have toxicity in the liver, or some other. I think this is overarchingly an important thing in drug development that everyone is interested in.

Q: Can you comment on the extent to which research funding and licensure outside the United States are able to support new vaccine development?

Phyllis Arthur (BIO): We're doing a deep dive on this in a separate place. We're trying to understand where investment is happening in vaccines. We have some preliminary data, but then we're almost done with a deep dive on what technologies are being invested in by which regions, not countries but regions. In a 10-year period, for the first 5 years, 50% of R&D and vaccines was dominated by the United States, and then about 25% Europe, 25% China or 25% Europe, 25% Asia. It's flipped since then. I'm seeing a huge percentage of investment in new vaccine technologies happening in China, and to some degree in Asia, and now the United States and Europe split the remaining 50%. Very surprising, a big change. I think we're trying to understand which technologies are being pursued where, and which diseases are being pursued where. There's investment going on in HPV in other parts of the world. There seem to be some diseases that some countries have probably taken on because of both national interest in preventing those diseases and interest in the global market for those diseases. And as we get the data more clarified, I'm happy to share what it looks like, but I've seen a shift in where R&D funding for vaccines is centered. And we have not yet seen the impact of the delays in NIH funding, the changes in strategy on NIH funding. We know the DOD has tried to keep up their work, but we know there were both delays in money going to the agencies, even to spend on grants, and changes in their strategic thoughts on which kinds of technology to support. We will start to see ripples show up in the next 6, 8, 12 months, in terms of how the pipeline looks.

Q: Are you able to speak to how companies are working with organizations like AAFP, AAP, etc.—to make recommendations?

Phyllis Arthur (BIO): Companies have been working with and presenting to the Vaccine Integrity Project (VIP) on the respiratory vaccines. They have been working closely with NAIIS as well as the medical societies to put together all the medical data plus the implementation thoughts on things like the respiratory season. I think they are looking at the HPV vaccine next. What do we do about brand new vaccines? VIP and the collection of medical societies could certainly look at the new indications for products that already exist. You can look at the published data included in their FDA filing. I think we're all trying to figure out whether we can duplicate the core parts of the ACIP process that were so important to the decision making. The CDC brought so much depth to understanding the pathophysiology of the disease, the epidemiologic presence, where is the disease in certain age groups, certain racial groups, certain parts of the country. The richness of that data is at their fingertips, and it educates the discussion of how the intervention fits into the overall public health schema. There's not a place that duplicates that. And normally, for these products that are going to be licensed in the next year or so, we would have been having a conversation and seeing the data presented, plus all that surrounding data, over the last two years [at the ACIP meetings, before that licensure]. We would not be walking into potential approval without having had at least a year or two of discussion of all these elements: feasibility, seeing the Phase II data, seeing the Phase III data, seeing the cost-effectiveness data, etc. One of the things we need to figure out as a community is the role of VIP and the partners, and the medical societies in particular, in evaluating data. Can they look at more than just published data from the companies on their clinical trials? Will they have sources that can share information on some of the background rates for the side effects? For example, it's important to understand how many people get Guillain-Barre from the disease versus how

many people get it in the trials. If we think of all the things that we do naturally in the ACIP working groups and the ACIP meetings, how do we mirror that? I think that's something that people are starting to think about, and it's important that we figure that out whether ACIP is not reconstituted — or even if it is but doesn't seem to be tackling the evaluation of new products in a more straightforward way.

L.J Tan (Immunize/NAIIS): Let's say the FDA does its job and scientifically evaluates those clinical trials and gives licensure to a vaccine, and it's based entirely on the Phase III clinical data.

Phyllis Arthur (BIO): It's based on all the phases. They look at everything.

L.J Tan (Immunize/NAIIS): So that means that vaccine is now licensed as safe and effective. Theoretically, what's to stop a manufacturer company from just going direct to consumer?

Phyllis Arthur (BIO): Nothing. Oh, not directly: They could go to plans, and before, we had the Affordable Care Act, which automatically linked ACIP recommendations to coverage in private plans, and then we had the IRA, which linked that same thing to Medicaid and Medicare Part D. Most plans automatically covered category B; routine recommendations (before we had shared clinical decision making) were almost always covered. So, companies always can do what they do on the drug side, which is go to individual plans, make the case and do the same with Medicaid. I think Vaccines for Children (VFC) is trickier; obviously you need that. The secretary can also write recommendations for things. This is what happened for COVID. They literally had a YouTube webinar, did a paper in New England Journal, and issued a recommendation. And they didn't even vote on it at ACIP. So, the secretary and/or the new CDC director, or both, have the power to not do ACIP. But yes, insurers absolutely have the power to decide on coverage for anything that is approved by the FDA. It's tricky because what we've been running into is that the scope of practice issues for various immunizers in statute in states may mean that you must have ACIP recommendations for, say, pharmacists to give a vaccine. So, we still must do our due diligence on the policy side of making sure those last few connections that are only ACIP, that affects scope of practice recommendations requirements, are now pointed to other sources of information, the FDA, medical societies, etc. We've all been working on that collectively across the country. But there are still some states where it's not done yet. So, if we want to make sure that every immunizer can immunize any eligible person, we might need to make sure that state legislation makes that scope of practice possible.

L.J Tan (Immunize/NAIIS): That reminds us about the alliances at the state level as well. And for those of you who are wondering, we will have a presentation by Angela Botticella from the Governor's Public Health Alliance at the Summit to talk about the alliances and what they're doing.

Q: Does the administration see a lag in R&D for vaccines and infectious diseases, in general, as a global security risk? China is outpacing the United States in R&D publications and patents — are company lobbyists making this point?

Phyllis Arthur (BIO): Yes. This is one of the reasons why we're saying these things but also trying to back them up with data. The reason I mentioned the project that I did before is that we want to show, we don't want to just tell. And it's important to share with them across a host of different therapeutic areas: What I'm saying about vaccine R&D is also true for cell

and gene therapy research and oncology research. There are rich data sources out there where you can say, “Look at the technologies.” One of the things that we want to point out is that some of the technologies in infectious diseases have huge utility in immunotherapeutic spaces. Stimulating the immune system to fight cancer is a cornerstone part of oncology research. These investments have multiple different dividends, if you invest in them. And this is not just [about] defending mRNA, but other technologies as well. mRNA is big, and if you look at what investments are happening, it's basic mRNA, it's a lot of different places. You're seeing research in infectious diseases, as well as oncology and other therapeutic areas across the board. It’s our goal is to make sure that it's well understood how technologies that have served us well across infectious diseases and other places are now getting away from American innovation.

Closing Comments, Phyllis Arthur (BIO): It's great for us to continue to focus on the pipeline, and I like that we went from the R&D side to the policy side, because I think what this community does really well is not just try to get ready for these exciting vaccines when they come, but also think through how to make a policy environment that makes sure that people who need them and are recommended for them can get them. One of the other things we'll try to fold in in the future is how people might be using delivery technologies. There are some cool delivery technologies that may make vaccines more heat-stable, easier to give, etcetera, that we're trying to understand better, so we might try to fold that in next year as we see more.

Announcements

- There is still time to register for the 2026 National Adult and Influenza Immunization Summit in-person meeting: May 19 – 21, 2026 at the Crowne Plaza Atlanta Perimeter at Ravinia in Atlanta, GA.
    - A few open registration slots are available at https://www.izsummitpartners.org/2026-naiis/.