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Subcommittee on Health

Hearing On

Maintaining America's Leadership in Biomedical Innovation:

FDA's Role in Advancing U.S. Drug Development

July 15, 2026

Chairman Griffith, Ranking Member DeGette, and Members of the Subcommittee, thank you for the opportunity to testify at today's hearing, "Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development."

My name is Dr. Cynthia Verst, and I serve as President, Design and Delivery Innovation, Research and Development Solutions, at IQVIA.

IQVIA is a leading clinical research services and commercial insights provider to the life sciences industry, with approximately 90,000 employees supporting more than 1,000 biopharmaceutical companies, from emerging innovators to large global companies. We work with thousands of clinical sites and investigators around the world to help engage patients, deliver high-quality trial data to regulators and bring better medicines to patients faster.

We appreciate the Subcommittee's focus on America's leadership in biomedical innovation, particularly early clinical development. Where companies initiate their earliest clinical trials often determines where investment, scientific talent, and patient access to new therapies concentrate.

IQVIA's vantage point on country competitiveness for clinical trials is practical and data-driven: we help sponsors design and execute clinical development programs, and we see in real time why companies choose one country over another for first-in-human (FIH) and other early-phase trials, as well as their global country allocation in later phases. Through the IQVIA Institute, we

also provide an annual Global R&D Trends Report that, combined with our CRO insights, shapes our testimony today.

The United States remains the most sought-after market for new medicines and thus a critical destination for clinical trials. For companies developing a globally important therapy, the value and importance of obtaining FDA advice and approval at any stage of development is key to commercial value, attracting further investment and fueling later stage trials.

Our trends data does indeed confirm that US share of Phase I country trial starts was surpassed by China in 2021, with China accounting for 31% and US 27% in 2025[i]. We took a deeper dive into this data, which reveals two issues for US policymakers to consider:

1. China's Phase I growth is driven predominantly by China-headquartered, pre-commercial biopharmaceutical companies translating their home-grown innovation more quickly from bench to clinic. China accounted for 89% of Phase I trial country uses by Chinese companies in 2025, and around 5% each for US and EU headquartered companies.[ii]. This trend points to an increasingly productive Chinese discovery to development ecosystem that is by China – for China.

2. While US headquartered companies conduct a majority of Phase I trials in the US, there is a steady trend of sponsors initiating their first-in-human trials in China or, more often, Australia to gain early confirmation of viability before coming to the US, due to cost and 'speed to signal' advantages. This trend suggests delayed access to promising treatments for American patients and underscores the importance of today's hearing.

When we talk about regulatory speed comparisons and enhancing American leadership, we offer an important distinction and the following recommendations:

1. **It's not FDA review times – but preparation that drives ex-US FIH starts -** Consistently sponsors, particularly emerging biopharma companies who drive >75% of new Phase I trial starts[iii], cite time and resources to assemble the IND package itself as a barrier to initiating trials in the United States. Many start their first trial ex-US while continuing to build the full IND package. The challenge is less the ultimate CMC and nonclinical data requirements and more the timing and threshold for US first-in-human trial initiation. We applaud the FDA and HHS for recognizing this challenge and taking meaningful steps to address through Operation Trialblazer.

    - Congress should further encourage FDA's efforts to define and use 'fit-for-FIH' minimum datasets to support "safe-to-proceed" decisions, which would speed US starts without compromising patient safety, as FDA would continue to require the data necessary to determine that a trial is reasonably safe to initiate in humans.

2. Focusing on "fit for FIH" at IND review will inherently defer some scientific and regulatory questions traditionally addressed at this stage to when they become more relevant to development decisions. While this will speed FIH starts, **it will necessitate more flexibility in FDA interactions and increased capacity for reviewers to be available in a more iterative way.** Reviewer feedback is especially critical for emerging biopharmaceutical companies who rely on advice for development decisions and to secure often staged investment needed to progress promising therapies through clinical development. Without

providing this support, the US may gain more FIH trials but see costly rework and delays as therapies advance to later stages.

- Congress should explore additional means to enable FDA to adapt review practices and increase capacity for scientific advice at stage-relevant times, particularly for emerging biopharmaceutical companies. For example, Congress could consider incentives like offering specialized early phase navigators for sponsors who commit to start trials in the US first.

3. Lastly policy efforts to maintain US leadership in biomedical innovation should **pair regulatory modernization with a broader, more pointed bench-to-clinic strategy**. America leads the world in biomedical discovery, but scientific breakthroughs do not help patients unless they translate to potential treatments that move efficiently into clinical trials.

   - While outside of the focus of today's hearing, Congress should explore policies that strengthen translational research, support the movement of academic and small-company discoveries into well-designed first-in-human studies, and connect NIH, NCI, ARPA-H, FDA, research institutions, community practices, and private-sector clinical development infrastructure to help ensure that promising discoveries generated here are also tested here. This includes supporting patient finding and trial matching across health systems via integrated electronic medical records with appropriate patient privacy protections, making community practice participation economically and operationally viable, and bringing clinical research more effectively into routine care.

If the United States is to remain the world's innovation engine, we must compete by making the path to high-quality evidence more defined and efficient—while maintaining FDA's high standards. A modernized IND review framework with tailored first-in-human expectations, more collaborative and iterative early FDA engagement, stronger translational infrastructure, and broader trial-access capacity would help sponsors start more early-phase studies here in the US while maintaining the patient protections that make FDA the global gold standard.

IQVIA is committed to continuing to work with Congress, FDA, HHS, sponsors, investigators, and patient communities to make the United States an even more attractive place for clinical research. We look forward to helping advance solutions that strengthen American biomedical innovation and, most importantly, help patients receive better medicines faster.

Thank you, and I look forward to your questions.

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[i] IQVIA Institute analysis, March 2026, Citeline Trialtrove, Jan 2026
[ii] See IQVIA Institute analysis
[iii] See IQVIA Institute analysis

Abbreviations:
FIH – First in Human
IND – Investigational New Drug application
CMC – Chemistry, Manufacturing and Controls