Ready Partner to Address the Zika Public Health Crisis

Syneos Health™

The Public Health and Research Response to Emerging Infectious Diseases in Our Global Developing Markets, Such as Zika Virus Infection, Requires Partnership Across the Industry, Including Public and Private Partnerships

Syneos Health is committed to improving global health and, as part of that mission, is poised to be the CRO partner of choice for clinical research in this area. We believe our organizational focus on therapeutic alignment supports this commitment. Each therapeutic area is represented within Syneos Health by a therapeutic area leader and staffed with medical specialists, project management staff and clinical operations staff to the level of clinical research associates.

This structure allows for our Infectious Disease and Vaccines teams to work in the area of their passion, develop a firm grasp of the best practices to apply study after study and be surrounded by supportive and knowledgeable colleagues that they work with habitually.

We believe that prioritizing investigational site needs and developing close relationships with the investigators and their research teams is critical to conducting the highest quality clinical research. This is evidenced by the CenterWatch awards for "Best CRO to Work With" in two consecutive rounds as voted by clinical study investigators and support for the Society for Clinical Research Sites (SCRS).

It is our belief that careful clinical investigation in the face of chaotic circumstances is essential to understanding how to contain the current public health crisis. Our combination of therapeutic alignment and investigator site intimacy helps us deliver on this goal.

We are ready to partner and assist in the effort to better understand Zika virus and are determined to ensure quality and robust data collection in this challenging setting. We are anxious to leverage our combination of experience, capabilities, global footprint and commitment to global health against this crisis in collaboration with our clinical and public health colleagues.

Syneos Health Has Developed a Unique Set of Capabilities That Make Us a Valuable Partner for Clinical Research in Zika Virus Infection

Acceleration of early phase studies, and vaccine immunogenicity studies

- Exceptional early phase experience in the U.S., Canada and Australia
- Focused capabilities in southeastern U.S. and Puerto Rico
- Capabilities in the Caribbean region
- Extensive pediatric experience

Vaccine commitment

- Dedicated therapeutic area team for vaccine and infectious disease
- Global expertise involving 60,739 subjects
- Catalyst Network of Vaccine Centers and Phase I capable centers
- Experience with immunizations in special populations, including pregnancy
- Studies within public health crises (Ebola)
- Active participation in vaccine programs for Zika virus
- Studies within public and private partnerships (BARDA)

Local expertise in Latin America

- Local presence
- Clinical expertise – local medical specialists
- >420 staff in 6 Latin American countries
- Investigator intimacy – solid network of experienced investigators
- Regulatory experience
- End-to-end development services: Phase I to IV and post approval
- 6 vaccine clinical trials involving 6,060 subjects

Epidemiology and Safety registries

- Public health/epidemiology expertise
- Broad scope of epidemiological study designs
- Unrivaled pregnancy exposure registry experience (multisponsor studies)
- Regional and vaccine-related experience
- Cross-sponsor collaboration
- Strong long-term follow-up

Latin America – Presence and Operations

Syneos Health is committed to expanding the scope of our clinical work in Latin America as an important part of our mission in helping develop the medicines people need worldwide. Latin America continues to emerge as an excellent environment for clinical trial conduct due to the network of experienced investigators, who can generate high-quality data, a solid regulatory framework that provides timely feedback and turnaround, and public healthcare systems serving two-thirds of the population for ease of enrollment. In addition, the region offers access to experienced specialists and thought leaders across various important therapeutic areas.

Solid Regulatory Framework

The six countries in which Syneos Health focuses its operations have well-established regulations and reliable processes in line with international GCP guidelines. This results in reliable data that can be combined with datasets from across the globe.

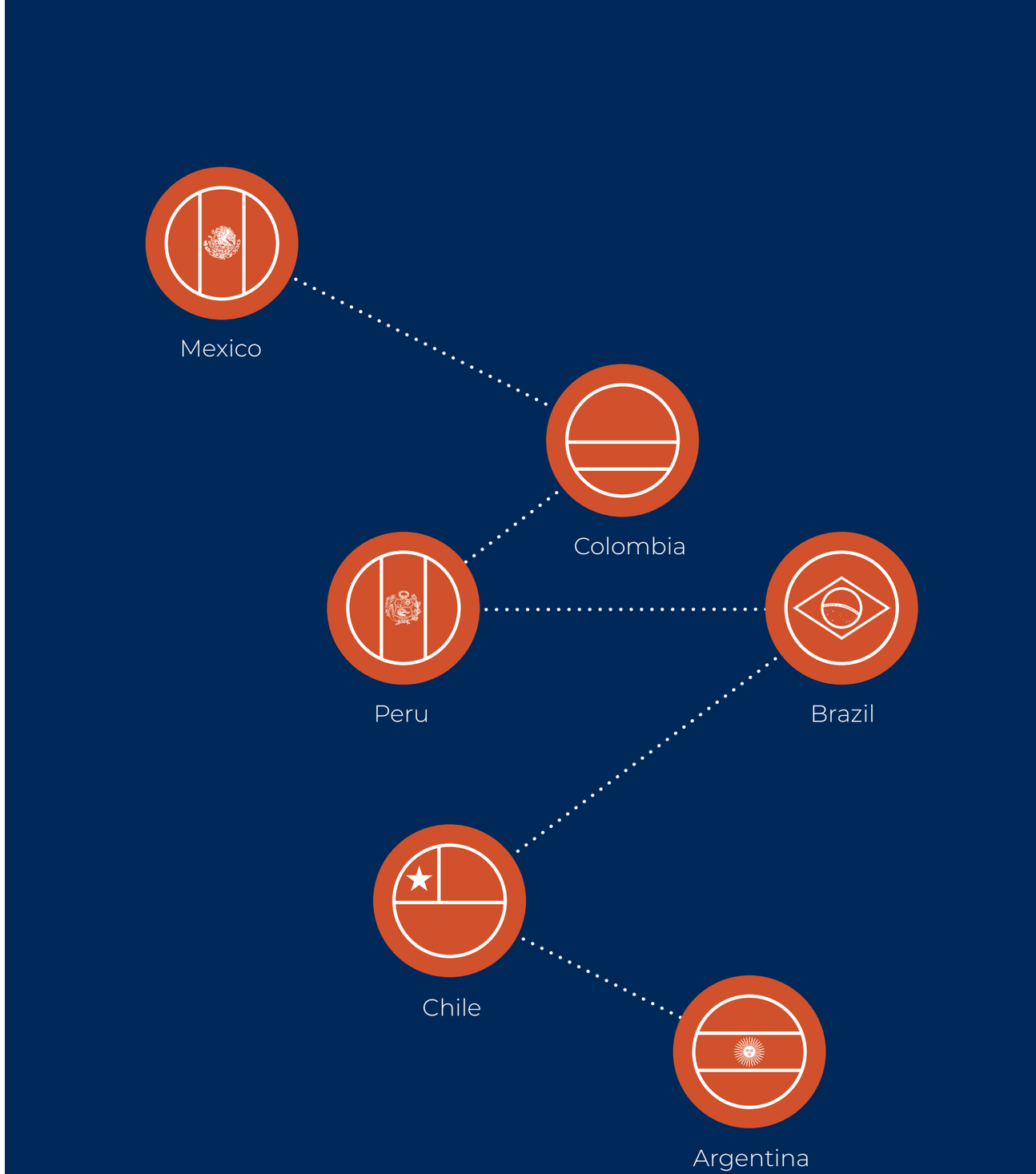
Unique Population Advantages

Compared with other emergent research regions such as Eastern Europe and South East Asia where multiple languages are spoken, throughout Latin America only Spanish and Portuguese are used. This simplifies regulatory submissions, the informed consent process and contracts, etc. In addition, time zones in Latin American studies are compatible with the U.S. – a distinct operational advantage.

Latin America – Capabilities

Syneos Health has had a presence in Latin America since 1987. Syneos Health Latin America is a leader among the CROs in the region, with assets including:

- Registered offices in all 6 major Latin American countries (Argentina, Brazil, Chile, Colombia, Peru, and two offices in Mexico)
- Additional coverage involving the full territory (eg, Ecuador, Guatemala, Panama, Dominican Republic, Costa Rica and other Caribbean islands with Syneos Health staff and Syneos Health collaborators)
- End-to-end Phase I to IV clinical studies, post-approval, real world, and health economics studies, and core clinical development services sourced out of Latin America
- Latin American based board-certified medical professionals and specialists as well as strong Project Managers and clinical staff who work with the broader organization for global trial delivery
- Strong and cohesive Latin American leadership team, providing local leadership and oversight to ensure successful delivery of trials for our customers
- Extensive experience in importation and exportation of samples and logistics for study supplies in each country



Syneos Health in Latin America

Phase	Total Studies	Total Sites	Total Subjects
I	7	68	971
II	61	3,600	15,891
III	96	9,985	53,712
IIIB/IV	30	4,311	48,696
Others	6	30	380
Total	**200**	**17,994**	**119,650**

Indication	Phase	Sites	Number of Patients	Countries
Hexavalent Pediatric Vaccine	III	2	2,139	Argentina (PM), Peru, Mexico
Hexavalent Pediatric Vaccine	III	6	1,190	Argentina (PM), Mexico
Hexavalent Pediatric Vaccine	III	1	299	Peru
Meningococcal Pediatric Vaccine	III	7 (1 central + 6 satellite)	400	Chile
Travelers Diarrhea Vaccine (adults)	III	9	2,036	Mexico, Guatemala

Proven Track Record and Clinical Experience in Latin America

Syneos Health has successfully conducted over 200 clinical studies that included investigational sites in Latin American countries, across all major phases of drug development.

Leveraging Global Experience

This combined experience in Latin America gives us insights into local best practices in vaccine and pediatric trials that we can leverage toward our customers' clinical development strategies and operational delivery.

In addition to our Latin American capabilities, we have relevant Syneos Health staff placed globally, including within the Asia-Pacific region:

- 19 Syneos Health offices in 13 countries with more than 600 staff with full-service offerings
- >470 studies conducted in the Asia-Pacific region, including 61 completed studies in infectious diseases indications with 140,000+ subjects enrolled in 21,000+ research sites

Vaccines – Global Experience

Syneos Health is committed to vaccine research as core to our mission to improve global health. We are a global company with highly experienced staff in vaccine development and conducting vaccine trials. We understand that vaccine clinical research in developing markets has its particular issues. Our vaccine experience, coupled with our presence and expertise, makes us an ideal partner for this type of work.

We have the flexibility, clinical experience, development knowledge and local expertise to manage a single study or a portfolio of studies. We are dedicated to supporting our customers in advancing the science and medicine required to develop new vaccines for critical medical needs.

Vaccine Capabilities

Syneos Health has vast experience of the inherent challenges of vaccine trials including:

- Informed consent including local and pediatric ethical considerations
- Enrollment of pediatric and elderly populations
- Complex site logistics resulting from the high volume of subjects on site during screening, enrollment, and vaccination days
- Collection of critical safety data through subject diaries (both electronic and paper)
- Collection and use of non-domestic data for regulatory approvals
- Concomitant data and safety database size
- Health system infrastructure
- Cold chain capacity in various global settings
- Laboratory sample handling, monitoring, and oversight to ensure quality of critical immunogenicity endpoints
- Rapid global study start-up and enrollment timelines
- Considerations related to global standard of care vaccination regimens and local variations
- Considerations regarding the interval between vaccine administration and development of immunity
- Well-developed network of vaccine-experienced sites, with proven track record of delivery
- Rapid response teams at set up:
  - We understand the need for rapid mobilization and thorough training of team resources at the beginning of the start-up period in order to ensure smooth delivery and data integrity
- Rapid subject identification:
  - Wherever applicable, potential subjects are initially prescreened by phone to decrease in-person screen failure rates and increase precision regarding the number of subjects pre-identified and ultimately enrolled. Study-specific subject identification and prescreening strategies and tools can be employed
- Experience with the unique considerations related to those vaccine studies that have an unblinded monitoring component:
  - Extensive initial and ongoing refresher training is provided to team and site staff
  - Separate management and escalation pathways for blinded and unblinded teams are established at the outset of a study

Vaccine Experience

Since 2010, Syneos Health has successfully conducted 46 vaccine related projects, involving 422 sites and 60,739 subjects, globally, across all phases of drug development.

We have the flexibility, clinical expertise and development knowledge to manage a single study or a portfolio of studies within a vaccine development program.

Clinical Operations Vaccine Experience since 2010

Phase	Total Studies
I	13
I/II	2
II	7
III	20
IIIB/IV	4
Grand Total	46

Vaccine Accomplishments

- ≥95 percent retention on all vaccine studies to date
- All key study milestones delivered on time
- Zero studies requiring reopening of a locked database thanks to our rolling lock process

Our experienced team handles and supports these unique trials, utilizing our Trusted Process® to ensure that we propose, implement and execute customized solutions for each of the trials, consistently providing quality deliverables on time.

Epidemiology and Safety Registries

Syneos Health has extensive global, observational, real-world research experience, with a broad scope of epidemiological study designs:

- Literature reviews
- Case series
- Case control
- Database analyses
- Retrospective chart review
- Cohort studies
- Registries:
  - Disease
  - Product
  - Pregnancy

Our expertise in the conduct of pregnancy exposure registries is unrivaled:

- Birth defect case review
- Cluster and signal evaluation
- Narrative writing
- Root cause analysis

We continue to manage the longest running pregnancy registry. Syneos Health was invited by the FDA to present on pregnancy registries best practices and to participate as a panel expert at their forum on this topic.

Our dedicated group has experience across registry designs, products, diseases and outcomes follow-up.

We are known for our pregnancy registry expertise and leadership in this unique niche. Our teams have overcome many challenges from open-enrollment, integrating data from multiple healthcare providers and complex subject-specific exposure assessments. Our registry best practices also extend to product and disease registries, where we have implemented several multinational and multisponsor projects.

Syneos Health CRO of Choice for Zika research

Vaccine experience in region

- 6 vaccine studies
- 6,000 subjects enrolled
- 60 percent pediatric subjects

Successful studies in public health crises

Successful Phase II H1N1 influenza treatment study in Latin America

Clinical studies in public-private partnerships

BARDA funded
Ebola clinical study

Epidemiology and Safety registries for long-term follow-up

Cross-sponsor, cross-product, pregnancy registry ongoing for >25 years

Latin American presence and expertise

- 420 staff in 6 Latin American countries
- 200 clinical trials
- 15,000 sites engaged

Syneos™ Health

If you would like to talk to one of our Latin American experts about how we can partner you in critical clinical research into Zika virus infection, please contact us:

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About Syneos Health

Syneos Health™ (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. The Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Learn more about how we are **shortening the distance from lab to life**® at syneoshealth.com.