

Vaccines

ICON's extensive vaccine expertise enables us to consistently beat aggressive vaccine start up timelines and enrollment goals while ensuring high quality deliverables within budget. We work across all sectors including biopharma, government and NGOs.



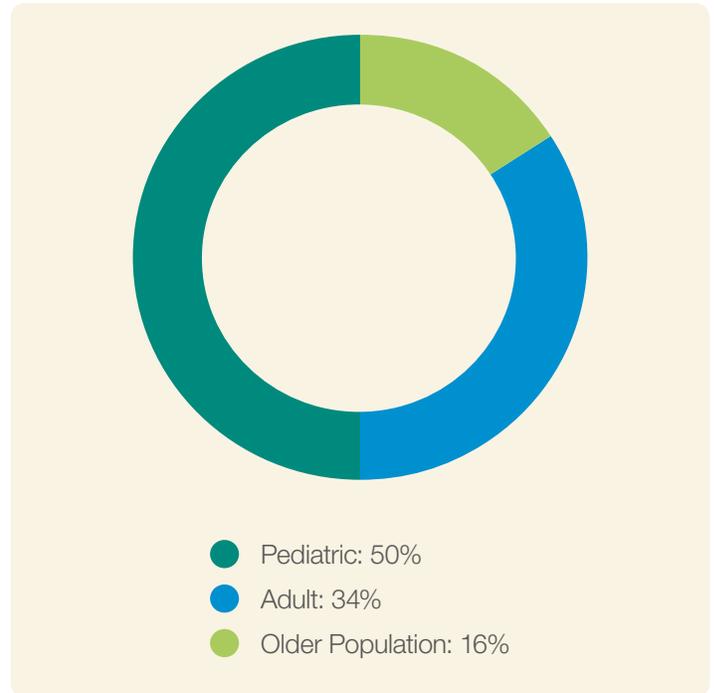
**ICON has supported
11 vaccine approvals**

ICON has extensive vaccine expertise and more than 600 vaccine and infectious disease trained staff to quickly mobilize and address our vaccine client specific needs. With over 80 years of combined vaccine experience, ICON's Vaccine Senior Management Team has supported 11 vaccine approvals, provides vaccine consultation, training and VP and/or Director oversight on all Vaccine studies.

ICON Vaccine Experience Past 5 Years

-  Experience includes over 200 clinical vaccine trials
-  >150,000 subjects
-  2,500 sites
-  In over 40 countries
-  In all age groups and multiple indications

- Seasonal Influenza
- Zika
- Pandemic Influenza
- Small Pox
- Pneumococcal Disease
- Yellow Fever
- Rotavirus
- Plague
- BCG
- Shigella
- DPT
- Toxic Shock
- Meningococcal Disease
- Tuleremia
- HIV
- Herpes Zoster
- HPV
- Malaria
- Glioblastoma
- E. coli
- Anthrax
- C. difficile
- Cholera
- Typhoid
- Pediatric Combination
- Adult Pertussis



The Vaccine Market

The list of vaccine-preventable diseases stands at 26, representing a major advancement in the quality of human health. Diseases like smallpox, polio, diphtheria and rubella have been defeated, while other widespread diseases have been reduced to just a few cases a year. There are many more vaccines in drugmakers' pipelines that may be on course to eradicate some of today's most difficult-to-treat illnesses. In Kalorama Information's report on the future of emerging vaccines, the group estimates that by 2020, emerging vaccines could account for \$24.7 billion in new sales.

Though sales of vaccines totaled less than two percent of the pharmaceutical market, the group thinks [and industry data supports] this market share will increase as technology advances bring about safer, more effective vaccines for a broader range of diseases.^{1,2}

Vaccine Efficacy and Disease Surveillance

ICON has extensive global, full service vaccine efficacy and disease surveillance experience with nine clinical studies at 815 sites, 54,000 subjects in pediatric, adult and older/elderly population.

Mega Vaccine Trial Experience

ICON's experts are ready to execute vaccine mega trials with recent experience on three studies, each 10,000+ subjects, in all ages, healthy subjects as well as high risk elderly subjects.

Industry Leader in eDiaries

ICON can successfully deploy effective eDiary solutions for your vaccine trial needs, with more than 50 studies using hand held devices. This includes two global mega vaccine trials of more than 10,000 subjects each utilizing the bring your own device (BYOD) model.



For more information on our extensive experience with wearables and BYOD in clinical trials please visit ICONplc.com/wearables

Vaccine Investigator Site Networks/Relationships

ICON remains committed to vaccine site partnerships as evidenced by our 2015 acquisition of PMG Research Network that spans 12 metropolitan US areas with over 48 physician practices, longstanding relationships with 12+ vaccine site networks and with ICON's Healthcare Alliance Strategy of 20 global multi-specialty healthcare and 16 SMO relationships with 100 sites and 900 physicians.

ADDPLAN

Adaptive Design Trials

ICON offers design, simulation and execution of adaptive clinical trials.

We are the only full service CRO that offers the knowledge, software, systems and global footprint to make adaptive trials a reality.

ICON's ADDPLAN is a fully validated, regulatory-compliant software platform that helps sponsors design, simulate, and analyse adaptive clinical studies. Currently licensed by more than 50 pharmaceutical and medical device companies, as well as regulatory agencies, including the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), ADDPLAN is central to ICON's operational expertise and global experience in adaptive trials.

ICONplc.com/addplan

Government and Public Health Solutions

ICON Government and Public Health Solutions (formerly ClinicalRM) is a prime contractor providing full service clinical development and staffing services across multiple agencies in the US Government.

In addition, ICON has over eight years of experience as the monitoring contractor for DMID/NIH, extensive experience working with multi-national public health organizations and global Non-Government Organisations (NGOs), and are a qualified provider for the Bill and Melinda Gates Foundation.

Recent Government and NGO funded projects include the following indications:

- Zika
- Avian Flu
- MERS
- Ebola
- Hantaan
- HIV
- Malaria
- Puumala
- Hep C
- Dengue
- VEE
- Y. Fever
- Shigella
- Chikungunya
- W. Nile

Africa network

Through our network of accredited laboratories, clinical research sites and strategic partners through out Sub-Saharan Africa, ICON can provide staff on the ground, providing rapid site selection, initiation, and staff training and patient enrolment in a total of 24 African countries.

Our experience in Africa includes more than 10,000 patients in GCP compliant Phase I-IV clinical trials with focus on infectious diseases, sickle-cell anemia and oncology.

On-the-ground support can also include:

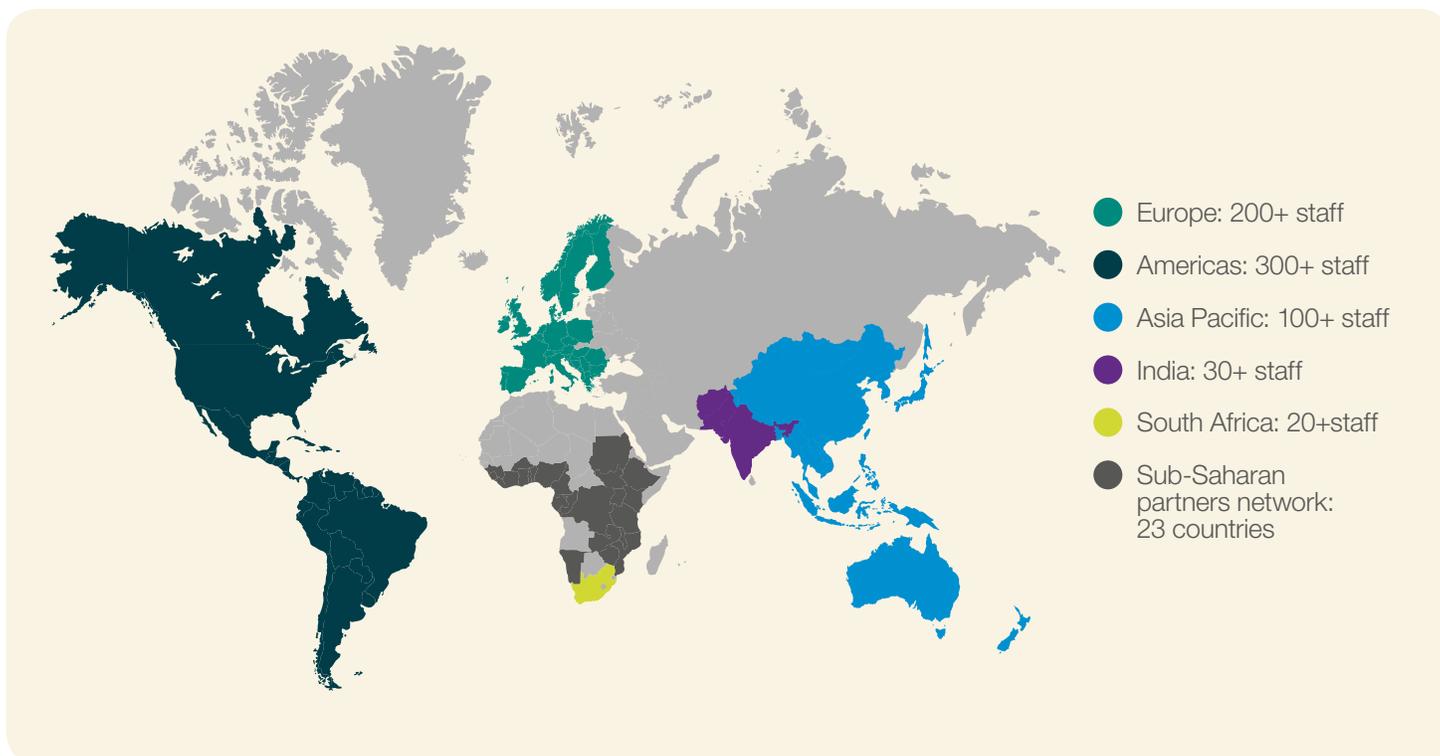
- Import and export of supplies and investigational products
- Medical transport (incl. ground and air support) and mobile labs
- Equipment, power generation, cold storage

Our longstanding relationships within sub-Saharan Africa uniquely positioned us to be among the only CRO service providers on the ground in the 2014 Ebola hot zone.

ICONplc.com/GPHS

Global Expertise Footprint – Vaccines and Infectious Disease

(Clinical Research Associates, Clinical Trial Management and Project Management)



Recognised Expertise

- Awarded ‘Best in Class’ CRO in vaccine research by the World Vaccine Congress in 2017, 2014. Highly commended or shortlisted the last 6 years.
- Qualified provider for Bill and Melinda Gates Foundation.
- ICON’s Vaccine leadership acknowledged as influential inspiring industry leader in both PharmaVoice and Vaccine Nation publications.
- 2017 Best Contract Research Organisation, Scrip Awards.
- Rated at, or above, 9 (on scale of 1-10, 10 highest score) for project delivery, project management proactivity and overall satisfaction for vaccines by our customers.

Best Vaccine CRO 2014 and 2017



*Shortlisted 2010, 2011, 2012, 2013, 2015, 2016

ICON supports the Greater Gift Initiative which donates **ONE** vaccine to **ONE** child every time **ONE** clinical trial volunteer makes the important decision to participate in a clinical trial.

greatergift.org



References

1. <https://www.fiercepharma.com/special-report/blockbuster-vaccines-of-future>
2. <https://www.kaloramainformation.com/Vaccines-9944129/>



Together we improve outcomes.

ICON is committed to solving global health issues by providing flexible and expedient clinical research services to government agencies and non-profit organisations.

ICON and You.
Partners making a difference.

[ICONplc.com/government](https://www.iconplc.com/government)





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About ICON

ICON plc is a global provider of outsourced development solutions and services to the pharmaceutical, biotechnology and medical device industries. The company specialises in the strategic development, management and analysis of programmes that support clinical development. With headquarters in Dublin, Ireland, ICON currently operates from 97 locations in 38 countries and has approximately 13,250 employees. Further information is available at [ICONplc.com](https://www.iconplc.com).