REDEFINING NONCLINICAL DEVELOPMENT

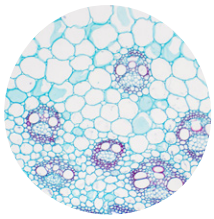
SparC of Innovation

Global Site Expansions
New Technology
Digital Transformation
New Efficiency Models

labcorp

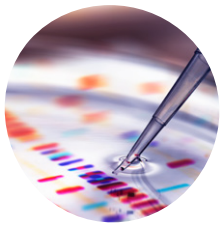
FALL 2021

Innovations covered in this SparC edition



This magazine features a few examples of the innovations and investments being made to help you find new ways to answer the questions you are pursuing.

Learn how your input is translating into real solutions in this issue of SparC of Innovation.



WELCOME

Making your breakthroughs possible with investments that matter

"All of the investments we've ever made, let alone made in the last five years, were based on what customers told us. That's why they've been successful. We're listening to our customers."

– Steve Street, President, Early Development

Moving with urgency takes determination, ingenuity and passion. It also takes innovating where it matters most. The decision to invest more than $700 million in the past five years in Early Development all started with listening to you. These initiatives have spanned the entire globe with a mission to expand capacity, enhance technology and produce new ways of working to ensure you have the insight, speed and flexibility you need to advance your development programs and pursue answers to life-changing breakthroughs.

"We are only successful as a company when our customers are successful," explains Steve Street, President, Early Development. "All of the investments we've ever made, let alone made in the last five years, were based on what customers told us. That's why they've been successful. We listen to our customers."

The reality is we can never stop innovating, growing and changing. Helping you take your novel ideas as far as they can go requires continuous innovation to provide you with the capacity and science you need. This is only possible by constantly striving to understand your current needs and anticipating your future desires as you continue to pursue new medicines, medical devices, chemical products and crop protection solutions.

You told us the Asia Pacific region is rapidly growing, and you need a way to bring new, advanced products into that region. So we doubled the size of our Shanghai facility (**page 18**) and equipped it with cutting-edge capabilities.

You told us the future of drug development will be dependent on cell and gene therapies (**page 12**), oncology (**page 16**) and inhalation (**page 20**). You also told us that groundbreaking research science (**page 24**) and *in vitro* models (**page 22**) are making this future a reality. It's the reason why we've been funding the latest technologies and expanding capabilities around the globe in each of these areas.

You told us that you need a research partner dedicated to providing services to the crop protection and chemical industry in the U.S. Therefore, we expanded our capabilities at our Greenfield, Indiana facility (**page 14**) and staffed it with specialists well versed in U.S. Environmental Protection Agency (EPA) regulations.

You also told us that you simply need to move faster. So we initiated efforts to digitize our back office (**page 6**), our pathology services (**page 10**) and your submission data (**page 26**). We also started tapping into new talent pools around the world through a remote workforce model (**page 8**). Now, these programs are fast facilitating a frictionless relationship experience.

"Innovation is happening around the world, in the cloud and everywhere in between," explains Street. "We collaborate with customers from the biggest pharmaceutical companies on the planet to the smallest, newest biotech with one or two people. Our partners are making advances in the chemical and crop protection, medical device and pharmaceutical industries. And we're making smart investments to ensure we're the partner of choice in each of these industries."

DIGITAL BACKROOM INFRASTRUCTURE

Harnessing efficiencies and intelligence for your study

"Our people and their scientific expertise are one of the strongest assets we have. What we're doing is taking that knowledge and building it into a system that our whole team can access automatically. It will enable us all to make better decisions, faster—for you and your study."

– Nancy Starke, Director of Business Optimization

> “What we’re really doing is connecting people and information. The work we do is incredibly complex, and it takes an enormous amount of information to design and execute a quality and compliant study.”
>
> – Matt Coutts, IT Executive Director

Let us pull back the curtain for just a moment. There are hundreds, if not thousands, of different actions and pieces of data that need to be completed, collected, processed, organized and tracked over the duration of your study or program. That information has to be accessible by dozens of different people working across various functions. And it has to be done for more than 9,500 nonclinical studies each year at our 20 global sites.

In order for us to provide you with the best experience possible, all of that information has to come together, quickly, so that every person you interact with has the information they need right at their fingertips.

This year will mark the first milestone in a multi-year project to digitally transform how we work behind the scenes to make it easier for you to do business with us. We are digitizing our study information, processes and communications, and automating steps wherever possible. It’s all aimed at simplifying your program experience.

Matt Coutts, IT Executive Director, is driving this digital transformation. “What we’re really doing is connecting people and information. The work we do is incredibly complex, and it takes an enormous amount of information to design and execute a quality and compliant study,” explains Coutts.

As we continue to invest and expand in both capacity and scientific resources, we thought it was the perfect time to also invest in how we connect our teams. The latest advances in information technology make it possible for every person you interact with on our team to have access to the same information and more easily collaborate on your studies. “Our people and their scientific expertise are one of the strongest assets we have,” explains Nancy Starke, Director of Business Optimization. “What we’re doing is taking that knowledge and building it into a system that our whole team can access automatically. It will enable us all to make better decisions, faster—for you and your study.”

The first step is to begin to connect the pieces. It’s a massive undertaking, but we’re on track to roll out the first phase toward a digitally connected infrastructure by the end of this year. And this is just the first important step. Subsequent releases will eventually connect the journey digitally all the way from your initial inquiry to the final report. The end result will be a seamless documentation of your protocol development and any subsequent changes to your project, making the whole process more efficient and transparent.

It’s also about making Labcorp a great place to work. We take great pride in hiring top talent to conduct your study, and it’s important to us that we fully enable that talent to be successful on your behalf. This digital transformation is an investment in the infrastructure that our people work within on a daily basis to provide you with the highest level of customer service and quality. By automating tasks that were once manually executed and providing connected access to our study resources, we’re making it easier for everyone to do their job and feel empowered.

While this digitizing effort is enabling our work behind the scenes, it’s focused on elevating the overall customer experience. “Ultimately, our goal is to shift as much of our people’s energy to working with you on your science,” concludes Starke.

A GLOBAL STAFFING MODEL

Science that never sleeps

When you have a global footprint spanning every time zone, there's no such thing as working from "9 to 5." You just have to know how to work the clock. That's the idea behind our Follow the Sun initiative. By creatively leveraging our global footprint to provide around-the-clock support services, we can trim days off your overall study times.

Lisa Biegel, Vice President and Global Lead, Safety Assessment Study Direction, Reporting and Data Management, shares a prime example of how this works to your advantage. "If it's late in the day in the U.K. and our technical staff needs to make a change to be implemented the next day, we actually have people in the U.S. that are still working. They can make that change to the database so the team in the U.K. can walk in at six o'clock in the morning and it's ready to go," explains Biegel.

In 2020, we started expanding the Follow the Sun initiative to our Labcorp Drug Development site in India. By the end of 2021, we aim to add a team of approximately 100 nonclinical specialists to support our lab sites and your studies around the world with data entry, analytics, quality reviews and reports.

Traditionally, these roles are located in the same facility as the labs they support. One of the disadvantages of this setup is it restricts you to the set space and local talent available. As a result, we had to get innovative in finding the room and the people power to accommodate your increasing study demand.

The COVID-19 pandemic shattered the traditional staffing paradigm. Like so many other industries, we learned that our nonclinical study support staff is just as effective working remotely as they are at the lab office, in some cases even more so.

In many ways, this wasn't a surprise. If you look at some of the other investments we're making, you'll see that we've been digitizing much of the data and tools our support staff work with on a daily basis.

> "It's the alignment of common practices and systems, which means you can have someone pick one task up in one location and when they clock off, you can have that same task picked up somewhere else. That only works when everyone operates in the same way in all of our locations, like we do."
>
> – Chris Clare, Vice President, Global QA

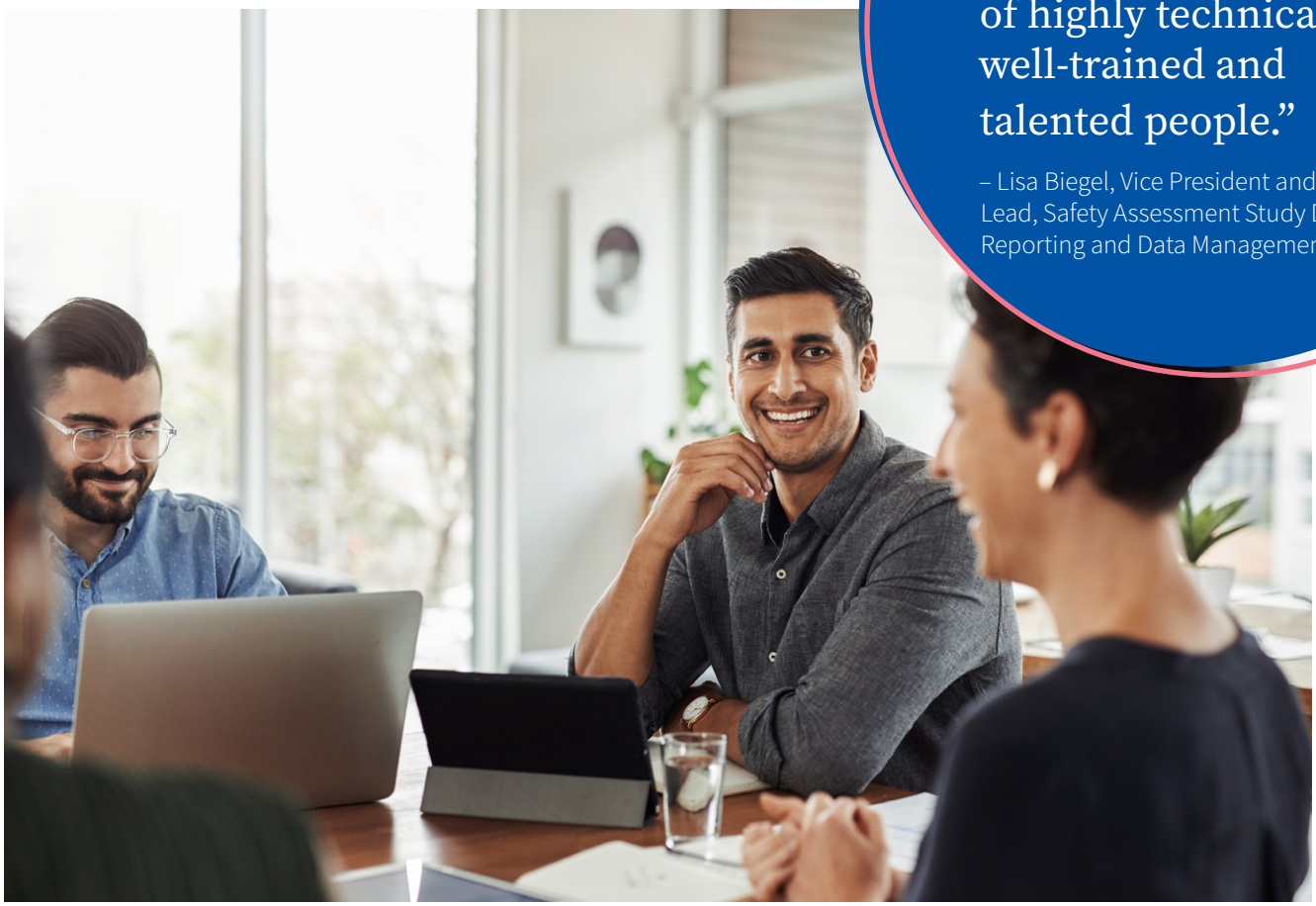
COVID-19 revealed an unintended benefit of this transformation. It showed us that the study support work can be done remotely, which means it can be done from anywhere. It simply made sense and aligned well to delivering with the urgency you expect.

So why India? Geographically, it has the benefit of being well positioned between the rest of our Asia Pacific sites and our European sites. It is the perfect complement and fit time-zone-wise to our staff that already exists around the world. More importantly, our infrastructure is already there.

Our 200,000 square foot India facility is already home to nearly 6,000 employees. We not only have desks and computers in place. We also have training programs that are easily adapted for nonclinical functions for our early development staff. "Having an infrastructure in place already, enabled us to get set up and fully operational in a matter of months as opposed to years if we were to start from scratch at a brand-new location," says Jamie Stevens, Director of Business Transformation for Early Development.

The decision to expand our nonclinical expertise to India was about people just as much as it was about capacity.

> “India has given us access to a new pool of highly technical, well-trained and talented people.”
>
> – Lisa Biegel, Vice President and Global Lead, Safety Assessment Study Direction, Reporting and Data Management

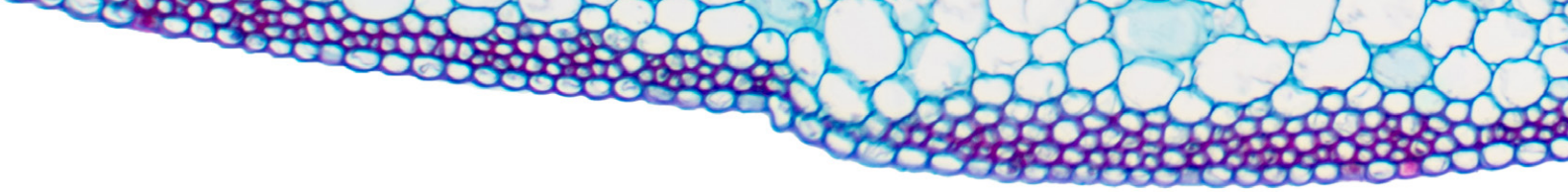


Our new nonclinical specialists are highly degreed, many with Ph.D.s and MBAs with relevant backgrounds in data entry, SEND analytics, pharmacokinetics and quality review as well as knowledge of study systems such as Pristima™ and Savante® and visualization tools and languages such as Spotfire®, Tableau® and Python®.

“At certain sites, there’s very low unemployment and very high competition for top talent,” says Biegel. “India has given us access to a new pool of highly technical, well-trained and talented people.”

While working during a global pandemic was the catalyst for shifting to a Follow the Sun model, we’ve been laying the groundwork for years by digitizing and harmonizing all of our processes and systems. “It’s the alignment of common practices and systems, which means you can have someone pick one task up in one location and when they clock off, you can have that same task picked up somewhere else. That only works when everyone operates in the same way in all of our locations, like we do,” says Chris Clare, Vice President, Global QA. “The fact that we are able to do this underscores how consistent we are in the way we do things and I think this will help drive even more staffing opportunity, because we can tap into talent from anywhere.” That is a model for truly leveraging science that never sleeps.

Our 200,000 square foot India facility that’s home to nearly 6,000 employees



DIGITAL PATHOLOGY

Welcome to the digital future of pathology

> "We're now able to contribute to a digital image database that takes customers from discovery all the way through clinical trial, so in the future a sponsor could essentially be able to digitally follow their own compound from the very beginning, to the very end of the research process."
>
> – Steve Van Adestine, Digital Imaging Services Manager and North America Lead

Imagine getting a phone call in the middle of your study from a scientist who is seeing something completely unexpected in your study results. You need to decide how to move forward and you need to do it quickly. You don't have time to wait for a shipment of glass pathology slides. Now imagine being able to not only listen to them describe what they see, but actually see it for yourself and review it with them live.

"That's one of the most powerful aspects of digital pathology," explains Matt Renninger, Global Head of Pathology and Statistics. "It puts us shoulder-to-shoulder with the sponsor, looking at the same images in real time, making good decisions together."

This level of collaboration is at the core of everything we do, and it's why we're investing an estimated $10 million into our digital pathology program. Our blueprint boasts 20 state-of-the-art systems installed across 14 global sites to create what just may be the world's largest singular, globally connected drug development digital pathology network.

We saw the potential of digital pathology as early as 2007 and started investing in it immediately, even though the technology wasn't quite there yet. Computer processing power wasn't powerful enough to efficiently handle the data, and a user-friendly image management system still hadn't been developed.

As a result, customer interest was minimal, but that didn't stop us from laying the groundwork for this important technology.

The global pandemic played a huge role in propelling digital pathology forward. As the world went into lockdown, sponsor pathologists couldn't travel to our labs for peer reviews and the logistics of shipping glass slides back and forth became complex due to global restrictions related to COVID-19. Suddenly, digital pathology was shoved into the spotlight and we were ready to go digital with sponsors. As soon as our pathologists finished their review of a study, they could share it with the sponsor's pathologist for an immediate peer review, saving weeks of shipping time and keeping studies on time despite the challenges of operating during a global pandemic.

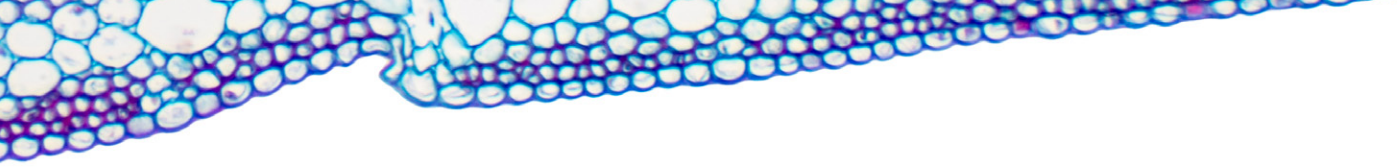
Real-time collaboration and nearly instant data transfer are just the tip of the iceberg. The real promise of digital pathology is in the creation of a comprehensive image database that will enable powerful artificial intelligence applications. However, not just any digital pathology program is capable of these advanced applications. It requires a fairly sophisticated strategy to design and implement an impactful program.

"It's a lot like a house," explains Steve Van Adestine, Digital Imaging Services Manager and North America Lead. "You have to build a strong foundation first before you can move on to some of the more advanced technologies like artificial intelligence."

One of the things that makes our digital pathology program unique for our customers is our commitment to building that strong foundation. Over the next year, we're investing in the hardware, software, infrastructure and staff to build a singular, globally connected network that will enable our customers to begin to harness the insight potential provided by digital pathology.

The first important piece of this investment is the equipment used to scan the slides. We're installing the Aperio GT 450™, the flagship digital pathology slide scanner from Leica Biosystems. This groundbreaking scanning instrumentation integrates directly into our histology process. The slides are automatically digitized as part of the study itself as opposed to waiting for the study to be completed. It's also incredibly fast, which means a lot to your development programs. And we have Deciphex Patholytix for the image management system, enabling digital slide transfer and peer review. We aren't just adding another step on top of old processes, we're streamlining everything.

With this global network set to go live by the end of this year, we're looking forward to exploring new artificial intelligence-based applications with you.



“We see the digital network we’ve built and the tools we’re starting to build as the foundation to completely transform how customers receive pathology evaluations in the future.”

– Matt Renninger, Global Head of Pathology and Statistics

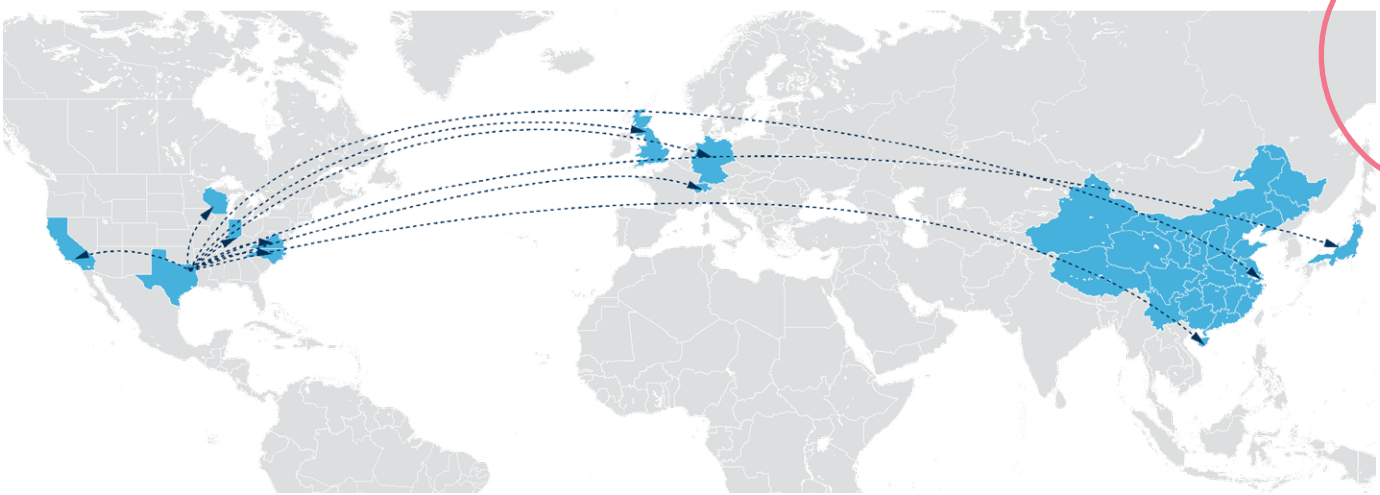
“Right now, clients are getting the digital database they need to be able to run deep-learning applications to answer their own questions. In the future, they’ll be able to have us answer those questions for them. That’s the roof of the house,” says Van Adestine. “We’re now able to contribute to a digital image database that takes customers from discovery all the way through clinical trial, so in the future a sponsor could essentially be able to digitally follow their own compound from the very beginning, to the very end of the research process. I’m not aware of this being done anywhere else in the industry.”

While many of the more exciting artificial intelligence applications are still down the road, we do have some tools we can already offer you today, such as quantitative analysis in addition to providing a qualitative analysis. “For example, we can measure the number of cells on a slide that express a specific protein to give you a more granular data set to evaluate,” shares Dan Weiser, Head of Global Special Pathology Services.

“We see the digital network we’ve built and the tools we’re starting to build as the foundation to completely transform how customers receive pathology evaluations in the future,” explains Renninger. This is really just the beginning. Ultimately, our vision is to digitize the entire histology lab, including study-based communication, file storage and transfer, and artificial intelligence exercises. But it all starts with this important first step of digitizing all of your slides and creating a globally connected image database.

Related reading

Learn more about our digital pathology capabilities.



Digital pathology network

1
single global network

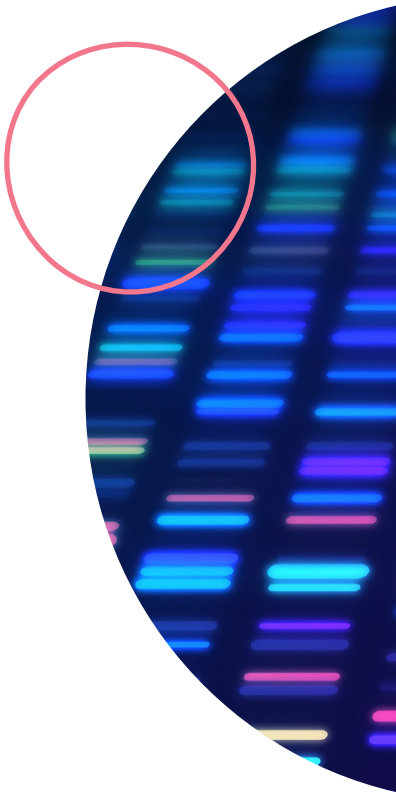
14
sites globally networked

20+
digital scanners installed

125+
anatomic pathologists in our global peer review network

NEW CELL AND GENE THERAPY SUITE

A macro investment in micro science



> "The market is evolving very quickly. This expansion affords us the flexibility to be scientifically driven and evolve with you as the market progresses."

– Ben Harmssen, Executive Director of Business Development

The science behind the development of gene- and cell-based therapies is as granular as it gets. Research at this level of precision requires the latest technology, state-of-the-art facilities and expert staff to produce optimal outcomes. In order to schedule more of your cell and gene studies and help you create more therapies to help patients, we have invested an estimated $9.2 million into a comprehensive nonclinical expansion of our Madison, Wisconsin site set to be ready for your studies by the end of the year. This complements other companywide investments dedicated to cell and gene therapy capabilities and support.

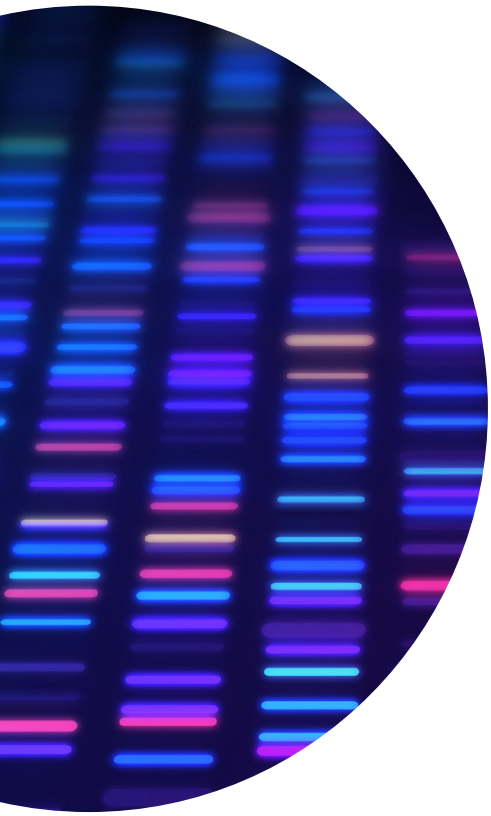
The ethos behind our expansion is to follow the advances in science to success. The cell and gene therapy market has been infused with global investor funding and continues to grow rapidly. Through investments in the leading technology, combined with a team of world-class specialists with expertise across the complex development continuum, you're placed in the unique position to give your therapies the best chance of moving smoothly through the development phases. "The market is evolving very quickly," explains Ben Harmssen, Executive Director of Business Development. "Science is going in a lot of different directions, very fast. We're working to put you in the best situation to address your unmet needs at this earliest point in development. This expansion affords us the flexibility to be scientifically driven and evolve with you as the market progresses."

The scientific innovation at our Madison site begins with the building itself. An entire floor is dedicated to Animal Biosafety Level 2 (ABSL-2) studies. The infrastructure contains five new, and four updated ABSL-2 flex study rooms, each of which is connected to its own dedicated high-efficiency particulate absorbing (HEPA) filtration system. This advanced filtration ensures a completely stable environment, which is imperative to protecting the welfare of immunocompromised test models, and by extension, protecting the integrity of your studies.

Perhaps the most promising new addition is the stereotactic surgery suite. "Stereotactic science is highly specialized and cutting-edge," says Maryland Franklin, Vice President and Enterprise Head of Cell and Gene Therapy. "It's a big request in the early development space. There's a need in this area and not enough expertise out there. We've had a lot of calls with clients, and they say they need that expertise. Now we can deliver it."

In the stereotactic surgery suite, scientists are able to deliver the cell or gene therapy directly into the brain of test models to enable delivery methods in line with approaches for clinical trials. Through this they gain insight on the treatment for conditions centered in the brain, like Parkinson's disease and Alzheimer's disease, with the goal of finding new treatments or potentially even a cure. Our brand-new suite equips us with industry-leading capabilities along with the space to schedule more of your stereotactic studies.

Within the walls of the new laboratories, you'll find scientists with the latest technology ready to explore groundbreaking areas of research for your cell and gene therapeutics. A notable example is the new X-ray irradiator, which can support a variety of applications in cell and gene therapy including the exploration of stem cells and how they behave within test models.



New dedicated ABSL-2 study space and stereotactic surgery suite are under construction at our Madison, Wisconsin site

What's the objective with all of this new technology and capacity? By following the science and investing in cell and gene therapy from early development through our clinical services, the ultimate goal is to accelerate your studies and help you develop life-changing treatments for patients. "We are pushing forward with the hope that what's tested here with our clients will one day improve patients' quality of life," says Brian McIntosh, Cell and Gene Therapy Lead. "The collaboration we do at every phase allows for therapies to come on the market to treat debilitating diseases. And when that happens, patients can receive that therapy and live longer lives. That highlights why it is so important to take these steps forward together. It is extremely imperative to ensure that quality of life happens."

Related reading

Learn more about our cell and gene therapy capabilities.

"We are pushing forward with the hope that what's tested here with our clients will one day improve patients' quality of life. The collaboration we do at every phase allows for therapies to come on the market to treat debilitating diseases."

– Brian McIntosh, Cell and Gene Therapy Lead

$9.2

million investment

5

brand-new ABSL-2 flex study rooms

✓

State-of-the-art stereotactic surgery suite

EXPANDED CROP PROTECTION AND CHEMICAL TESTING

For those in relentless pursuit of our planet's sustainability and the welfare of humanity

We've been ramping up our product testing support at some of our European sites over the past few years to meet the needs of the rapidly growing crop protection and chemical industry. Now, we're excited to announce a multimillion-dollar expansion at our Greenfield, Indiana campus in the U.S. that enhances your options even further to access more crop protection and chemical toxicology studies on a global scale.

The Greenfield facility is ready with a broader scope of specialized capabilities designed to enhance overall animal welfare as well as your study results. For example, the newly appointed vivarium rooms contain optional European-style housing that's more spacious, along with an expanded play area. There is a new dietary formulation lab with new analytical equipment and storage capabilities for flexible onsite dose adjustments and diet mixing. And we've initiated a more efficient and eco-friendly cage-washing method that's aligned to our sustainability mission. It all means advanced innovation that's built in and focused on generating better studies for you.

The primary reason our Greenfield facility made sense for this expansion is due to its long history in general and reproductive toxicology. We were able to draw upon that trusted knowledge and expertise to quickly expand available capabilities for you. "Customers have been running toxicology and regulatory studies under GLP at our Greenfield campus for multiple years. It's a highly successful facility that's home to a core base of specialized and experienced scientists. This provides a strong foundation as we expand our crop protection and chemical portfolio in the U.S. There's a tremendous amount of experience that our customers can tap into to drive their products to market," explains Andrew Hill, Executive Director and Global Lead, Crop Protection and Chemicals.

One area of particular interest within toxicology is Developmental and Reproductive Toxicology (DART). The newly upgraded reproductive toxicology area will effectively run your Extended One-Generation Reproduction Toxicology Study (EOGRTS), a DART study that has seen a surge in demand in recent years as customers adjust their development programs to meet changing regulations.

When it comes to regulations, we have cultivated a well-rounded team of regulatory specialists to guide you through every step of the compliance process. Our regulatory consulting team boasts a breadth of experience in a wide range of disciplines, from research and development, to independent consultancy, to the Environmental Protection Agency (EPA). No matter what regulatory procedures your study undergoes, we have the insight to make sure it meets every standard.

Your feedback has been instrumental in our decision to invest. We have heard your requests for a more robust crop protection and chemical presence in the U.S. "Customers are excited that there will be additional capacity within the marketplace. And our U.S. customers are very excited that they will have something in their own country from a supplier that they trust," describes Joanne Miller, Executive Director Global Crop Protection and Chemical Sales.

This investment also serves international customers looking to market their products in the U.S. You'll find a global support network is included in our expanding Greenfield operation with the capacity and support team for the development of your products worldwide. "Customers from Europe, and particularly customers from Asia, have been keen for us to establish this expanded capability in the U.S. They want global registration and what they really want is to work with one partner who is able to do it all for them," explains Hill.

Helping you develop products you can bring to markets around the world is what motivated us to grow our crop protection and chemical presence in the U.S. At our expanded Greenfield facility, you'll find development that ensures regulation compliance as well as expert guidance in both the U.S. and around the world.

> "Customers from Europe want global registration and what they really want is to work with one partner who is able to do it all for them."
>
> – Andrew Hill, Executive Director and Global Lead, Crop Protection and Chemicals

> "Our U.S. customers are very excited that they will have something in their own country from a supplier that they trust."
>
> – Joanne Miller, Executive Director Global Crop Protection and Chemical Sales

Related reading

Learn more about our crop protection capabilities.

Learn more about our chemical capabilities.

All-new dietary formulation lab for flexible, onsite dose adjustments and diet mixing

PRECLINICAL ONCOLOGY RENOVATION

Fully invested in your fight against cancer from the very beginning

> "Two drivers that are critical in the early discovery phase of oncology are speed and insight. We can address both even better now by having the new, larger facility and latest technology."

– Scott Wise, Executive Director of Preclinical Oncology

According to a recent study from the American Cancer Society, over 19 million people were diagnosed with cancer in 2020. Cancer reaches every corner of the globe and touches way too many of our lives. And as the search for answers advances, all eyes are on oncology research and this growing drug development field full of new technology and treatment candidates.

We are committed to supporting you in your fight against cancer in the largest therapeutic area in drug development today. That's why we've invested in a total renovation of our preclinical oncology facilities in Ann Arbor, Michigan. This investment increased the space from 27,000 to 37,000 square feet and equipped our laboratory with the latest innovations to keep your studies and our scientists at the leading edge of technology. The additional space includes new cell culture labs, wet labs and vivarium facilities, all dedicated to your preclinical oncology studies.

This investment enables us to conduct more studies and ultimately help more patients. "With the expansion comes our ability to add new services to help our customers," says James Norman, Executive Director of Business Development at our Preclinical Oncology, Antibody Reagents and Vaccines branch. "Now that we have a bigger laboratory, we can expand the number of analytical machines that we already have and we can bring in new ones, thereby being more flexible and efficient for our customers."

Not only do our enhanced facilities enable greater capacity, we can schedule studies faster as well. "Time is critical for our clients, and ultimately the cancer patients who will benefit from new therapies," says Scott Wise, Executive Director of Preclinical Oncology. "Sponsors are looking to get data, and if our capacity was constrained, we wouldn't be able to turn around their projects and give them the data they need. Two drivers that are critical in the early discovery phase of oncology are speed and insight. We can address both even better now by having the new, larger facility and latest technology."

A notable feature of our larger facility is the brand-new vivarium, which houses 13 state-of-the-art bio-bubbles. The bio-bubble design features a high-efficiency particulate absorbing (HEPA) filtration system that provides the positive pressure environment necessary to ensure that specialized immuno-compromised models remain safe and pathogen free, which preserves the integrity of your study. Additionally, we can reconfigure their arrangement without having to pause any studies taking place inside of them, increasing the flexibility of our workspace and keeping your timeline on track.

The new vivarium also contains 37 individually ventilated racks that can hold up to 30,000 models concurrently and supplies a third level of filtration, delivering greater safety along with greater capacity. "We have an ultra-clean environment that keeps our immuno-compromised models very safe," says Wise.

When it comes to which treatments we explore in our new space, your feedback is crucial to our decision making. The updated facilities enable us to conduct research in high-interest areas like biomarker science, where we utilize GeoMx® Digital Spatial Profiler by Nanostring to gather data in greater detail than ever before, even down to specific portions of tumors.

We are also one of the only contract research organizations to employ a Small Animal Radiation Research Platform (SARRP) by Xstrahl, a scaled-down version of a clinical radiation treatment instrument that allows us to research novel radiation combination treatments in a preclinical setting.

We are dedicated to helping you find more answers in the fight against cancer. By expanding our preclinical oncology facility, we're able to give you access to the latest technology to keep moving your science forward and ultimately making it even more possible to change patients' lives for the better.

Related reading

Learn more about our preclinical oncology capabilities.

State-of-the-art bio-bubble design features a HEPA filtration system

37,000

square feet

13

bio-bubbles

30,000

concurrent model capacity

ASIA PACIFIC EXPANSION

Broadening the borders of drug development

4.7 billion. That's the approximate population of Asia as of 2021. That number represents about 59 percent of the total world population. People are living longer and with that comes the demand for improved healthcare. With the Asia Pacific region accounting for about 15 percent of the drug development pipeline today, it's no wonder that it is growing at a double-digit rate.

As we watched the rapid growth of the development pipeline in the Asia Pacific market along with the increased drug development study requests that resulted, we knew the time was right for an expansion to meet your growing needs. The investment in our Asia Pacific operation with a $6.6 million renovation of our Shanghai, China facility aligns perfectly with the mission to move health forward and bring life-changing breakthroughs to people around the world.

"We had more clients coming to us wanting to do work, but we were completely full and were scheduling months into the future," says Matt Renninger, Site Lead for Early Development in Shanghai. "Labcorp launched the initiative to increase capacity as well as acquire new tools and technologies to help better serve our clients' increasing needs." Completed in mid-2020, the renovation resulted in increasing the study capacity by over 50 percent.

With new capacity comes new capabilities. "We were set up to do the basics, which was the right place to start. After seeing customers

$6.6

million
investment

50%

more study
capacity

Renovated lab space in our Shanghai facility

"After seeing customers request more sophisticated study work, we moved quickly to add advanced technologies to deliver more complex analyses and support our clients' changing demand."

– Matt Renninger, Site Lead for Early Development in Shanghai

request more sophisticated study work, we moved quickly to add advanced technologies to deliver more complex analyses and support our clients' changing demand. That's a huge shift," says Renninger.

One of the most exciting areas you can now access from our state-of-the-art space is biologics. We installed an immunology and immunotoxicology research laboratory—which we call the I&I lab—where we can collaborate with those of you who need immunophenotyping, cytokine analysis and other assays to support the development of immunomodulators.

We are also equipped to offer jacketed external telemetry (JET) studies, which are required to satisfy safety assessment regulations in China. JET is a leading method of data collection that monitors cardiovascular endpoints. By incorporating JET during the development process, you're assured that you have the data you need during filing.

When it comes to filing, it's crucial to have a team of regulatory experts on hand. Our team of regulatory specialists have a wealth of localized experience to help you seamlessly file your study with China's National Medical Products Administration (NMPA). You can get help with global filing as well from a team that has supported studies for more than 50 Investigational New Drug (IND) applications with the NMPA and U.S. Food and Drug Administration (FDA) over the last seven years.

"I think that's the beauty of having the team in China. They have local and global knowledge and can efficiently help clients do the work and then submit dual filings for the U.S. and China," says Renninger.

The paint has barely dried on our Shanghai renovation, but we are already planning further additions to support our clients from our Asia Pacific operation.

The future of healthcare in the Asia Pacific region is incredibly promising. We are thrilled to help you move health forward by bringing new answers and new medicines into this flourishing region. "We are creeping close to where we're going to be full again. So we're focused on being a step ahead, continuing to expand to meet your growing study demand," says Renninger.

Related reading

Learn more about our Shanghai facility.

NEW INHALATION BUILDOUT

Breathing new life into inhaled medicines

Taking an inhaled medication can be as easy as taking a breath. This simple and painless drug-delivery method has always been a preferred option for respiratory drugs. The inhaled medicine market is booming. There are more than 100 pharmaceutical compounds in development for the treatment of respiratory ailments, such as asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF) and idiopathic pulmonary fibrosis (IPF). It is also quickly becoming the method of choice for a variety of more diverse and systemic therapies as an alternative to needle injections or other invasive applications, which are less desirable to patients—such as for Parkinson's disease, seizures, diabetes and analgesics.

We are responding to your growing need with an estimated $10 million investment that expands your inhalation toxicology study options at our Huntingdon, U.K. site.

While taking an inhaled drug can be easy, developing one is an incredibly complex and challenging undertaking. The science behind developing an oral or dermal treatment is comparatively more established and easier to execute. Aerosolization, however, is a difficult scientific process that requires a cutting-edge lab space implemented by highly skilled specialists to ensure success. "The principal premise of an inhaled drug is to aerosolize it effectively, consistently and reproducibly," says Simon Moore, Global Lead of Inhalation Sciences and Engineering.

Inhalation expansion under construction at our Huntingdon site

> "Bringing together the deep scientific knowledge, specialized technology and the whole infrastructure was essential to ensuring you get an innovative and cohesive experience in a very complex development space."
>
> – Simon Moore, Global Lead of Inhalation Sciences and Engineering

"Bringing together the deep scientific knowledge, specialized technology and the whole infrastructure was essential to ensuring you get an innovative and cohesive experience in a very complex development space."

The trend toward inhaled medicines drove the necessity for a dedicated workspace and staff and was the impetus of the expansion of our Huntingdon, U.K. site. This state-of-the-art facility now staffs a team of 40 inhalation experts and features a modular buildout of six new, dedicated inhalation testing rooms. What's the benefit of a modular buildout? "A concrete building would have required 12 to 18 months to construct. The commission of the innovative modular building enabled us to be up and fully functional in less than nine months. It was the right decision to help you bring more life-saving breakthroughs to patients quicker," explains Moore.

In addition to an expedited rollout, the expanded lab space ensures we have additional capacity and flexibility to schedule an increased number of your inhalation safety studies. You can also find full-service support from early efficacy through regulation compliance. "Because of the greater infrastructure, our ability to support your programs has increased considerably. As of mid-2021, we've already delivered in six months what we typically do in a full year," illustrates Moore.

With increased inhalation capacity and capability, you can also explore the use of inhaled medicines as a secondary indication, which is currently a popular trend in the inhalation market. This method enables you to utilize a drug that's been previously developed for a non-inhaled application—most commonly oral or dermal—and repurpose it to an inhaled form in order to capitalize on new opportunities for respiratory ailments. For example, you can repurpose a fungal dermal medication into an inhaled drug to treat respiratory lung infections.

Developing an inhaled medicine is a highly intricate undertaking. With this investment in expanded inhalation capabilities, you can now get a cutting-edge and a comprehensive development process to more easily ensure your product's success.

Related reading

Learn more about our inhalation capabilities.

~$10
million investment

6
dedicated inhalation rooms

>40
inhalation experts

30% MORE GENETIC TOXICOLOGY SPACE

Leading the way in new study options rooted in the 3Rs with genetic toxicology and *in vitro* alternatives

New space now available at our Harrogate facility for your genetic toxicology studies

"It's all about enabling our customers to develop safe products. Whether that is a pharmaceutical, chemical, cosmetic, aerosol or medical device."

– Julie Clements, Global Lead of Genetic Toxicology

Your continuing requirements to find new options for product testing inspired us to grow our capacity for genetic toxicology and *in vitro* alternatives. It's an investment focused on enabling you to quickly and effectively respond to changing regulatory requirements as well as the evolving industry sentiments regarding product testing. And it's enabling our researchers to innovate faster around the 3Rs principles (replacement, reduction and refinement) with a keen focus on bringing you more in *in vitro* alternatives and robotic-driven study solutions.

In order to provide more access to cutting-edge *in vitro* solutions, the size of our genetic toxicology labs in Harrogate, U.K. has been expanded by more than 30 percent. In addition, new spaces are now open at our U.K. sites in Shardlow and Huntingdon to provide you with even more options. By broadening study capacity for you, our investment is creating a sustainable evaluation process rooted in the 3Rs that's adaptable for many different industries' product development pipelines.

"It's all about enabling our customers to develop safe products. Whether that is a pharmaceutical, chemical, cosmetic, aerosol or medical device," says Julie Clements, Global Lead of Genetic Toxicology. We are driven by a focus on humanity–enhancing testing methods to ensure safer products and a safer world.

With the new space comes a suite of innovative assays to look at different endpoints from cardiovascular to pulmonary. By exploring cell cultures, 3D tissues, *in vitro* alternative methods and options for screening flow cytometry for multi-endpoint assays that go beyond a "yes" or "no" answer, we can reveal more insightful mechanistic information.

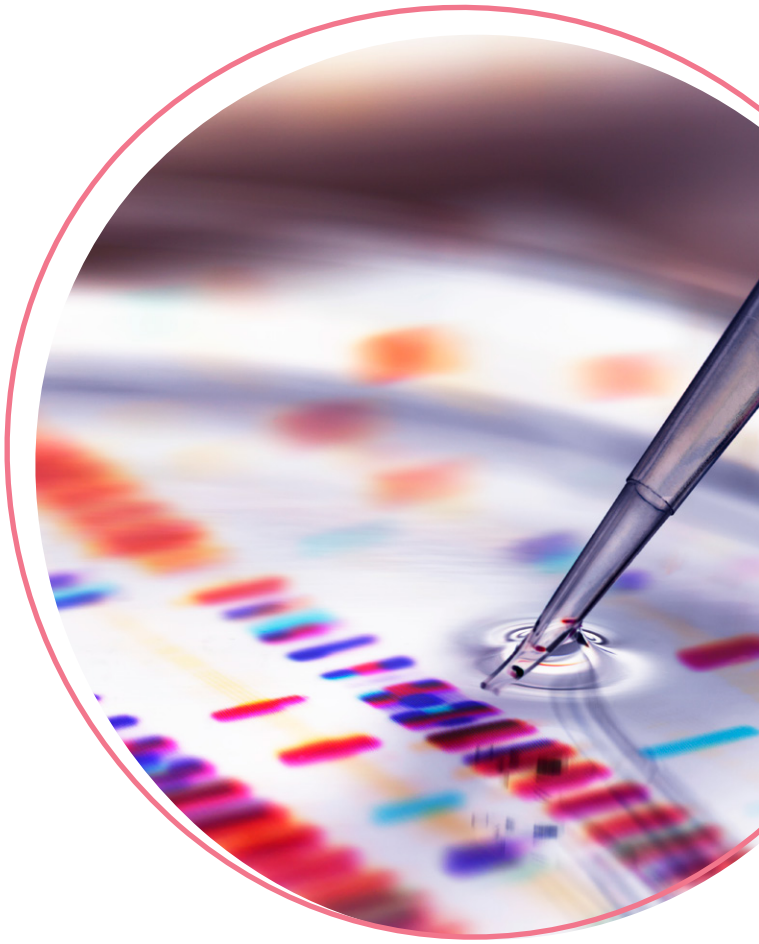
Your research at the expanded genetic toxicology facilities is already garnering positive results. "Collaborating with customers to push the boundaries in science is what keeps customers coming back," says Joanne Miller, Executive Director Global Crop Protection and Chemical Sales. "Because they know they're getting scientific expertise from a team that has their ears to the ground about what's coming up next."

One exciting area of growth is in aerosol science. We are exploring cutting-edge solutions and robotics that comply with new regulations and provide models of human tissues. "By using airway 3D models for oral tissue models and lung tissue models, these breakthroughs can bridge the gap between *in vivo* and *in vitro*," explains Miller.

As the world's demand for safe products increases, the demand for innovation in genetic toxicology and *in vitro* models increases along with it. In our aim to be more than a partner, we have not only recognized this need. We have transcended it. Our recent investment in genetic toxicology is already resulting in flexible solutions for novel practices within our laboratories, which means safe products for consumers. And we see a bright future ahead.

Related reading

Learn more about our genetic toxicology capabilities.



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European-style animal housing

NEW VIVARIUM WING IN MÜNSTER

More space for science and personalized medicine to run wild

Immuno-oncology. Biologics. Cell and gene therapies. This is the future of medicine. It's more personalized, more complex and driving an increase in demand for highly technical nonclinical studies that require study models that most closely resemble the human body. Oftentimes, it's nascent science that demands a new study that hasn't even been invented yet.

That's why innovation is built into the very foundation of our renowned nonhuman primate (NHP) center of excellence in Münster, Germany. We're right there alongside our sponsors at the leading edge of personalized medicine. "We are constantly investing in our resources to ensure our customers have access to the latest advancements in science and technical capabilities and studies are conducted with superior animal welfare that exceeds industry expectations," explains Lars Mecklenburg, Site Lead and Executive Director Safety Assessment. Our most recent $19 million expansion is no exception.

Encompassing 41,000 square feet, the expansion includes a state-of-the-art vivarium with 26 study rooms for conducting general toxicity, safety pharmacology and reproductive toxicity studies, as well as staff office space. "It's really about quality, not quantity," explains Mecklenburg. "The facility design provides the space and flexibility to keep implementing new ways to elevate animal welfare that has a direct correlation to study outcomes. It's for our clients who keep pushing the boundaries of healthcare and the patients who urgently need these next medical breakthroughs."

We designed this next-generation research facility based on our 15 years of experience with housing NHPs in social groups and taking into account our key learnings since the implementation of the European group-housing regulations in 2006. The expansive vivarium now features an innovative design to accommodate new ways of behavioral enrichment and training. It represents a prime example of how we keep your studies ahead of industry trends. "With this expansion project we had the opportunity once again to push innovation even further with a focus on improving study outcomes for clients," explains Theodor Lucas, Scientific Proposal Manager. "We asked new questions such as, 'How can we further optimize the cage design?' and, 'How do the animals use the space that we provide to them?' and moreover, 'How does all of this impact study data and outcomes?'" The final installation creates a more natural zoo-like environment with lots of structures to climb and sit on and new materials to play with—which translates to more enrichment and enhanced study outcomes.

Modern office spaces

When it comes to advancing our technical capabilities, patients and our customers are our North Star. “More often than not, it’s our customers that come to us with a very specific study need in mind that they are struggling to place because it is outside the standard box for whatever reason. Maybe there is a specific endpoint or a specific administration procedure,” explains Lucas. “We think about it together and, oftentimes, come to a solution that brings us to the next level of scientific expertise we are then able to establish and offer to more customers.” This new facility sets us up well to explore potential medical breakthroughs for the more complex and rare patient conditions.

“When we see a customer challenge or new medical trend, we react to those needs,” says Mecklenburg. Twenty years ago, it was therapeutic antibodies and biologics. Today, it’s cell and gene therapies. “All of these novel drugs need to be investigated nonclinically first. That’s what drives our innovation,” Mecklenburg continues. “New medicines may require very specialized routes of administration, such as for treatments that may need to be administered below the retina or directly into the human brain for indications of the central nervous system.”

What’s most exciting is that investments in innovative techniques tend to have a ripple effect across our global footprint. And we can easily see what we will learn here will eventually be employed for your studies being performed at our other locations. For example, many years ago, we developed a specific study design for reproductive toxicity assessment and became a leader in that study type. We transferred that knowledge to our Madison, Wisconsin facility. “We called it Münster in Madison,” says Mecklenburg. “Same conditions. Same procedures. The staff collaborated and learned from each other. Now we have a replicated offering at both locations available to more clients.” Our model for harmonizing practices across sites has been integral to our mission of innovating to consistently offer the best solutions to you and the patients you serve.

Related reading

Learn more about our development and reproductive toxicology capabilities.

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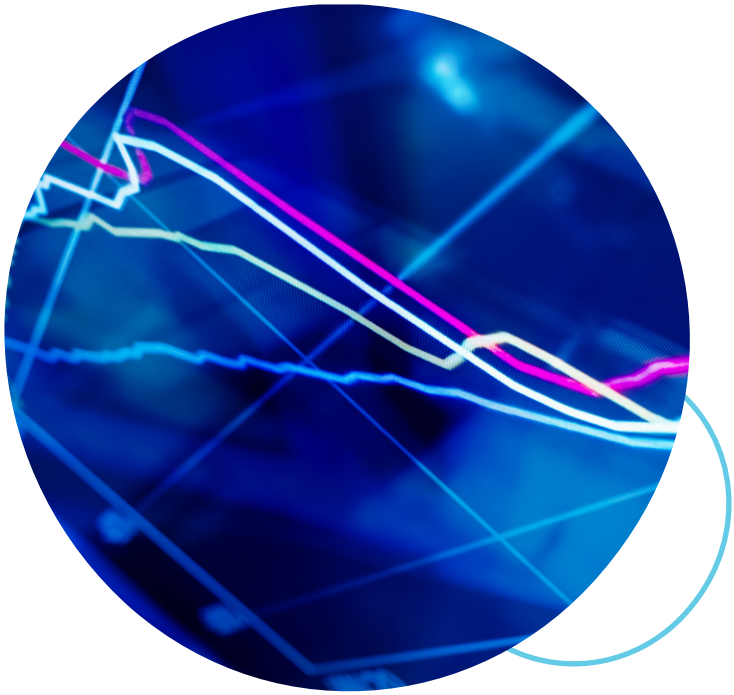

SEND 3.1 UPGRADE

Special data effects that magically reveal your study side effects

In 2016, the Food and Drug Administration (FDA) made the move to digitization by requiring the collection and submission of datasets for nonclinical studies to be filed electronically in a standardized, consistent format. Known as the Clinical Data Interchange Standards Consortium (CDISC) Standard for Exchange of Nonclinical Data (SEND), this format is now the digital standard for submission-ready datasets for general toxicology, carcinogenicity, safety pharmacology, legacy and any relevant non-GLP studies.

When the original FDA provision came through, we made sure you were ready. We have long been involved with the SEND consortium as well as the FDA and Pharmaceutical Users Software Exchange (PHUSE) working groups that develop and maintain the standards guides for the industry. This enabled us to build our SEND infrastructure years before 2016. We built it with a clear vision to maximize the utility of your study datasets by ensuring your studies are compliant to the new regulation and set up to leverage the power of your data in innovative ways. Today, our customers have received over 125 billion data points and we facilitate more than 1,500 SEND data deliveries each year.

Now, as we grow our global footprint, we are elevating you to the next generation of SEND capabilities at every site. This way, you have access to all of the benefits of SEND regardless of which of our nonclinical facilities is conducting your study. We have already activated the latest version, SEND 3.1, at all eight of our nonclinical safety assessment sites worldwide. “In SEND 3.1, you can expect everything previous versions of SEND delivered, now at hyperspeed,” says Megan Bausman, Director, Global Data Management Solutions. “It is reducing turnaround time for a submission-ready SEND dataset from the typical 12 business days to only one. That speed and power is the new standard for all of our nonclinical studies and sites.”

But we didn’t stop there. You told us you want even more of your study data presented in the SEND format. Our SEND service expansion includes two additional services, automated data delivery and data conversion. “Why limit the power of the SEND standard to studies started since 2016? Or only to in-scope studies for the regulatory requirement?” asks Bausman. “With our newer SEND service offerings, you have more options available to take advantage of the SEND model.”

Automated data delivery is our innovative solution for providing you with near instant access to your in-progress study data. It enables you to monitor your ongoing studies and swiftly make decisions during

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time-sensitive points of your study, such as the in-life phase, when making smart decisions early can save you time and money in your development program.

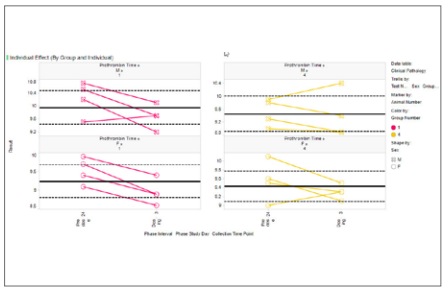
Lisa Biegel, Vice President and Global Lead, Safety Assessment Study Direction, Reporting and Data Management, illustrates how automated data delivery can play a critical role in the development of your studies. “SEND helps our clients make smarter decisions. For example, early study indications can sometimes uncover something unexpected that may lead to a key strategic decision in a drug’s development. You don’t want to wait three months for the conclusion of the study and final report when you can get the data on day four of a study. When you can see the data, you can make those important decisions faster.”

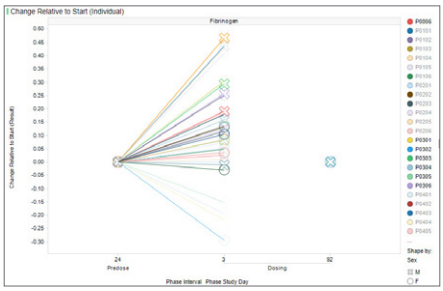
Another benefit of SEND is its power to easily interrogate and visualize an extensive collection of data. This SEND feature is called data conversion. By looking at your broader library of studies, SEND can give you valuable insight regarding your asset portfolio to set a more informed strategy going forward. “It’s not only about looking at a single study. It’s about looking across all of your studies to see what is there,” explains Jason Pitzer, North American Regional Manager of Data Management. “What stories does your collective of data tell you? You can look at studies within a program, across a species or creatively at any combination of the fields in the SEND dataset. You can go back in time and convert the study data of your historical studies as well. Ultimately, you can utilize this goldmine of data and gain value from it that you may not have realized was there.”

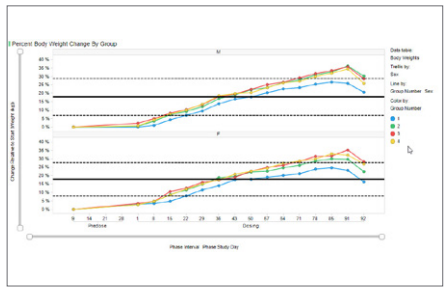
Our mission is to continually push to break the mold of what digitization can do, which will further strengthen and facilitate a frictionless development pipeline for you.

Related reading

Learn more about SEND 3.1.







Digital visualization tools

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labcorp