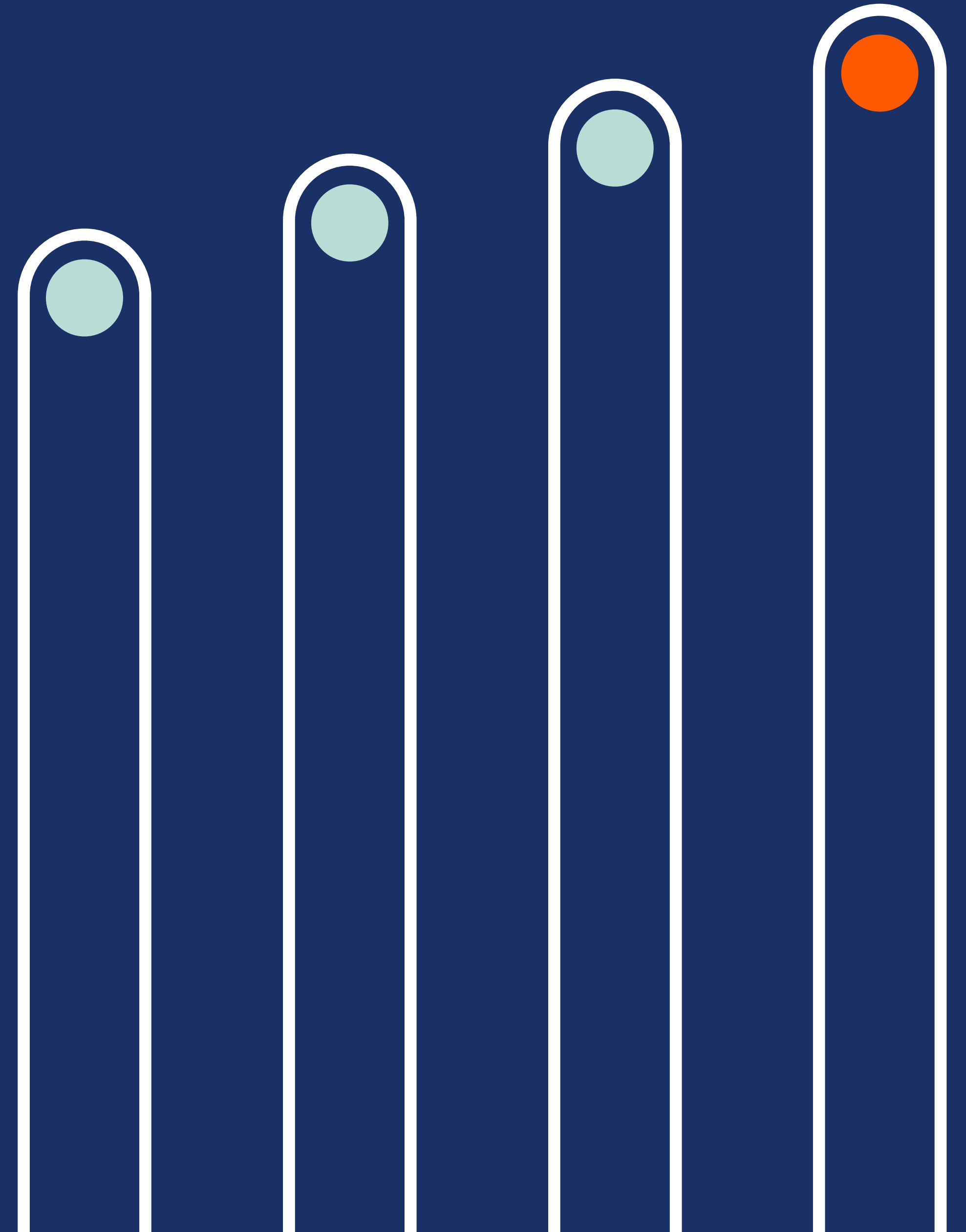


eBook

Powering diagnostics at scale

Large custom projects



Introduction

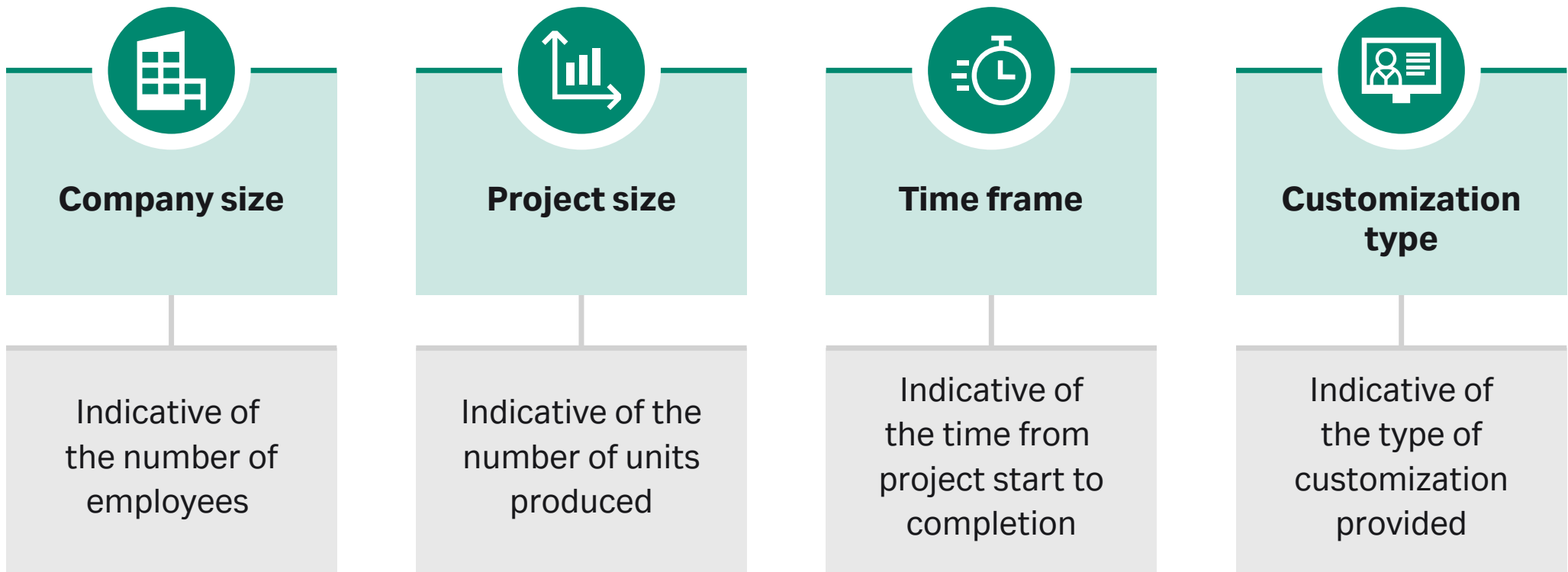
Each of your molecular or immunoassay development projects is unique. So, you need solutions tailored to your specific needs. Cytiva has a proven track record of delivering innovative diagnostic design and development services. This case study eBook highlights large, real-world examples of successful custom service collaborations with diverse clients.

From assay design and optimization to high-throughput production and validation, our comprehensive capabilities and technologies can help you overcome challenges and deliver impactful outcomes. Whether you are a scientist or business leader working on or looking to accelerate your diagnostic assay and kit development, you can depend on us.

 [Download our small-mid scale projects eBook](#)



Scope and scale of the project



Plug and play lyo-stable beads for disease assays



Company size
Medium



Project size
Large



Time frame
4 months



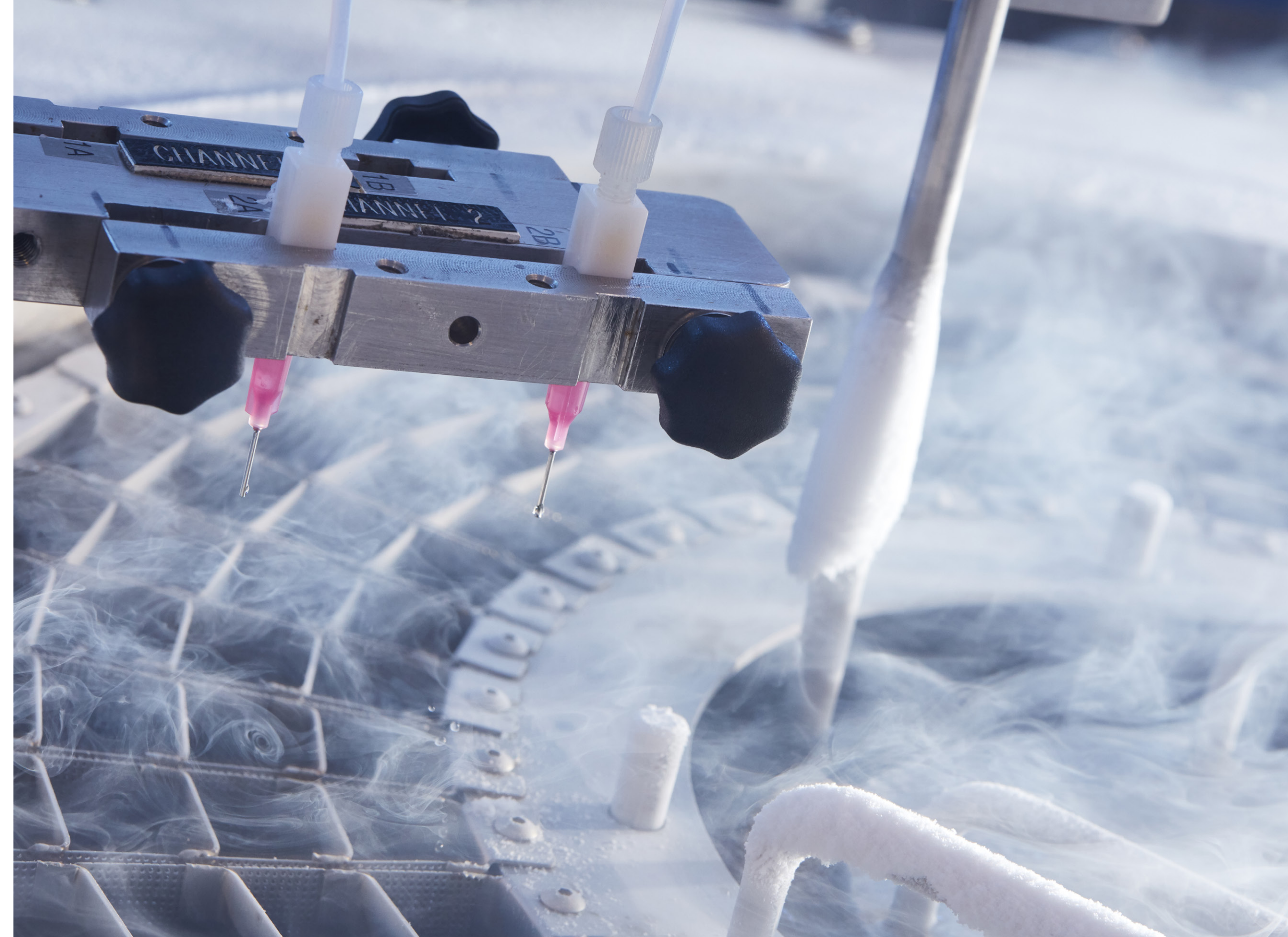
Customization type
Service

Project story

- The customer has a point-of-care device that is loaded with cartridges.
- Each cartridge contains all the molecules needed to perform a particular assay. For end-user convenience, the cartridges are designed to be stored at room temperature.
- They asked Cytiva to provide lyo-stabilization services to manufacture the beads that go in the cartridges.
- Our lyo-stable technology allows molecules to be freeze dried without harming their functionality.
- Soon after the project launched, the COVID-19 pandemic created a sudden need for shortened timelines and increased production.
- The Cytiva team worked closely with the customer to optimize processes to meet the pace and manufacturing demands.



[Learn more about Lyophilization](#)



The customer tried using lyophilization to make room-temperature stable beads for their assay device. But they couldn't produce the beads with high enough quality. So, they turned to Cytiva. Our working relationship with them was especially good because we had a local specialist who spoke their native language.

Martina Kahl, Diagnostics Account Manager

✉ *Speak to Martina to learn more: martina.kahl@cytiva.com*

Turning your idea in to reality



Project story

- The customer had an idea to develop a multiplex lateral flow test that would test for multiple respiratory tests on one strip.
- The customer provided the reagents to use in the test, and asked Cytiva to design and build the product itself.
- Cytiva worked closely with the customer with frequent calls to make sure that the customer was always informed and satisfied.
- Cytiva produced prototypes for the customer's internal testing and approval.
- The final product worked, met all the customer's criteria, and was delivered within the customer's timeframe.



Learn more about our immunoassay development services



We met the customer informally at a conference in late 2021 and started working with them in early 2022. We had a close collaboration and spoke to the customer every week. We even shared our working documents with them.

Klaus Hochleitner, Global Product Specialist, Diagnostics

✉ Speak to Klaus to learn more: klaus.hochleitner@cytiva.com





Magnetic beads for a massive test

 Company size Large	 Project size Large	 Time frame 4 years, ongoing	 Customization type Product
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Project story

- The customer was developing a blood test that would screen for 50 different, but related, diseases.
- The customer chose to work with Cytiva because of our experience, flexibility, and wide range of customization options.
- The customer asked for custom magnetic beads packaged for them in a specific buffer.
- Cytiva produced several iterations to optimize the product.
- Our ability to scale up and provide security of supply made the customer feel comfortable working with us.
- The customer is asking for a new version of the magnetic beads and is discussing working with Cytiva on other parts of the project.

 [Learn more about our magnetic bead conjugation services](#)



We dedicated a small team to this customer, but we made sure that everyone on the team was very knowledgeable, nimble, and responsive to the needs of the project. They visited our manufacturing facilities and were impressed at how regimented and well-documented all their processes were.

Max Hogan, Diagnostics Account Manager
✉ *Speak to Max to learn more: max.hogan@cytiva.com*

Complete, lyo-stable kits from start to finish



Company size

Large



Project size

Large



Time frame

**4 years,
ongoing**



Customization type

Product

Project story

- The customer has a device that can perform real-time cell analysis. They needed kits made for the device that their customers could use when they worked with device.
- Originally, the customer asked Cytiva to make just part of the kit, but once they learned what we could do, they expanded our role to make the entire kit.
- A key part of Cytiva's role is making lyophilized beads to go into each kit. The customer simply tells us what to include, and we make it.
- Cytiva then compiles the complete kit including printing and attaching the customer's labels.
- Customer satisfaction was achieved in part because we purchased equipment specifically for their project and we helped solve their shipping issues.
- Cytiva and the customer traded visits to one another's manufacturing plants to keep up quality and maintain open communication.



[Learn more about our lyophilization services](#)



This project was large to begin with, but it became even larger over time. We were originally asked to make five kits. The customer was so pleased with the first set that they keep asking for new ones. We're up to 14 or 15 kits now, and we will continue to keep develop kits as long as the customer wants.

Steve Nelson, Diagnostics Account Manager

✉ *Speak to Steve to learn more: steven.nelson@cytiva.com*

When they said “big,” they meant it



Project story

- The customer built a new sequencing platform and needed consumable products to be used with the platform.
- The customer had strict requirements about the qualifications and education of the people working on the project, and Cytiva met these criteria.
- For the project, Cytiva was asked to lyophilize some reagents and package them.
- The project is so large that Cytiva built a facility to do the work. We even purchased our largest freeze dryer for the project.
- The project began in 2020 during the height of the pandemic, so Cytiva arranged virtual tours of our facilities so that the customer was comfortable with the progress and quality of work.
- Now, the customer and Cytiva have multiple meetings a week and the customer has regular on-site tours of the facilities.
- The project is ongoing, and the customer is pleased with our service.



Learn more about our contract manufacturing and kitting services



We won this project because we have such great coverage across different areas of expertise and capabilities. We knew going in that the project was big, but it turned out to be a lot bigger than we imagined. We were still able to comfortably manage the size.

Math Davies, Diagnostics Account Manager

✉ Speak to Math to learn more: matthew.davies@cytiva.com





A project that doesn't end, and that's great

 Company size Large	 Project size Large	 Time frame 4 years, ongoing	 Customization type Service
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Project story

- The customer was launching molecular diagnostic tests in lyophilized format.
- The original request was for Cytiva to lyophilize just a couple of tests, and the customer thought that would be the end of the project.
- However, the customer was so pleased with what Cytiva provided that they asked for a few more tests. And then some more.
- The customer is a large company who could make the tests themselves, but they still chose to work with Cytiva.
- We share working files with the customer, have face-to-face meetings, trade site visits, and generally have open communication with them. We also perform regular audits.
- The project is still ongoing. The customer's product is doing well commercially, so more tests are expected.



Learn more about our full range of diagnostic services

When we started this project, we thought that it was going to be small. The customer even thought that it would be short-term. But the project grew and is still ongoing. Fortunately, we have the capacity to grow with the customer's needs.

Math Davies, Diagnostics Account Manager

✉ Speak to Math to learn more: matthew.davies@cytiva.com

More information

 Checklist: 10 essentials for choosing a collaborator for diagnostic assay

 Download our small-mid scale projects eBook

Checklist

1

How healthy are a collaborator's procurement, supply timelines, and infrastructure?

Lab deliveries can severely impact your development timeline and can disengage customers at the commercialization stage. Before committing to a project, ensure effective risk assessment and mitigation strategies are in place and that the potential collaborator has a cross-functional, data-driven commitment to supplier risk management.

3

Can they scale with you?

Ask whether a collaborator has the capacity and scalability to see you through to manufacturing stages. Are the facilities capable of accommodating manufacture of everything from single-buffers through multi-component sets for both low- and high-throughput needs? Can fluctuations in demand for the different products be managed effectively and with minimal disruption to supply?

5

Can a collaborator help you reduce environmental impact with sustainable solutions?

Sustainability is becoming a priority across the industry and a commitment to supporting it can gain you a business advantage. See whether a collaborator offers sustainable solutions. For example, lyophilization (also called freeze drying and cryopreservation) removes water from a substance at a low temperature. A product or sample that has undergone lyophilization can be shipped and stored at room temperature, which is safer and more sustainable. The process also maximizes the product's stability and shelf-life.

Find the right collaborator for you

What level of ongoing service, support, and expertise can you expect?

Timely access to knowledge and expertise to help you with the development and launch processes and to guide your workflow is essential. The ability to troubleshoot challenges when things don't go to plan and to find solutions directly with scientists and technical teams is an advantage that some potential collaborators have.

Will a single-supplier approach work for you?

Using one supplier for all diagnostic needs reduces the complexity of the supply chain and saves time and resources because you need to validate only one supplier. You may even be able to negotiate better terms through economies of scale. Make sure any company that you want to use as a single supplier offers everything from components to services and can support your entire workflow from initial development and clinical trials to manufacturing and commercialization.

What's their track record?

Working with a collaborator who has evidence of success and experience in similar projects may help reduce development timelines. Ask a potential collaborator for examples of similar projects undertaken and their successes and learnings to determine if they can handle your project.

2

10 essentials for choosing a collaborator for diagnostic assay development


Imagine you have an idea for a lateral flow device and need help with development. Or maybe you need support scaling up the commercialization of a molecular assay. Or perhaps you're simply searching for a collaborator you can depend on now and in the future.

The race to commercialize diagnostic tests is faster than ever. Molecular and immunodiagnostic tests using nucleic acid and protein assays in a lab-based or point-of-care format are now an essential component in the evaluation and early detection of many diseases. Working with an organization who you trust allows you to share insights, access equipment and specialized infrastructure, and benefit from broader expertise and skills without capital investment or development time.

Use this checklist to find the right collaborator for you.

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cytiva.com



Can you tour the facilities?

Be sure that you can tour a facility in person or virtually. That way you can check the infrastructure, equipment, and capacity of a collaborator. Seeing the operation and talking with the people who work there can provide reassurance that your assay will be in safe hands and that production can meet the expected demand.

Can they offer a full-workflow solution?

A collaborator should be able to support you from project start to completion. They should have a diverse portfolio of reagents, membranes, magnetic beads, and services. If they do not develop all the components or excipients in-house, they should have access to reliable contractors via a strong network to make the process as smooth as possible. You should ask if you can use your current reagents in the development process.


What training workshops are available?

Some companies conduct workshops to co-develop an assay, maximize the collaboration, and help position you to take the development forward. These workshops can also provide insights for future projects.

Do they provide support when you need it?

Operating in a global environment means you might not be located physically close to a manufacturing site. In fact, multiple manufacturing sites may be needed to optimize timelines and assay quality. In these cases, you probably can't be located close to all the sites. Make sure a potential collaborator offers virtual tours, timely updates, and round-the-clock technical support that coincide with your operating business hours. Also check that they have a strong supply network for shipping efficiency, which will positively impact your project's success more than the site location.

Click here for more information on Cytiva's diagnostic services



eBook

Powering diagnostics at scale

Small- to mid-size custom projects





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