

# To Support Go/No-Go Decisions in Early Drug Development, Inotiv Got It Together — Fast

Pharmaceutical and medical device companies are always under pressure to improve research productivity. Increasingly, they rely on contract research organizations (CROs) for access to specific expertise, laboratory capacity, and scalability to accelerate progress. Inotiv is a broadly capable, service-oriented CRO that provides on-time, high-quality data and insights that drug developers need to succeed in a competitive marketplace.

The COVID-19 pandemic has intensified the pressure on sponsors as they search for a vaccine. Inotiv has been instrumental in supporting multiple sponsors at the earliest discovery stages of advancing vaccine and antiviral candidates to help address the pandemic. Before a drug is tested in humans, drug developers must do as much as they can to ensure the drug will be both safe and effective. If done organically, equipping a company with all the testing capabilities, services, and expertise required to help drug sponsors gather the evidence they need to determine whether their drug candidates are worthy of clinical trials would have taken decades. Yet Inotiv's founders assembled this integrated, complementary suite of resources and capabilities in less than three years and now serves hundreds of pharmaceutical and device companies. How did they do it?

## A Perfect Storm

In the past decade, the largest global CROs engaged in a series of mergers and acquisitions that changed the CRO landscape. This flurry of activity left a void in midsize providers in this space, presenting an important opportunity. In order to field a comprehensive, competitive R&D offering, the new company needed to muster a broad range of specialized services, facilities, and experienced scientists.

## Starting With a Solid Foundation: BASi

Bioanalytical Systems, Inc., started out in the 1970s as an instruments company producing state-of-the-art electrochemical detectors and HPLC systems for universities and pharmaceutical companies. Over the years, it added a contract services division for bioanalysis and pharmaceutical testing and joined forces with a toxicology and pathology house to become a sizable GLP, GCP, and GMP compliant contract laboratory. Today, BASi still exists as a NASDAQ-listed umbrella company and provides scientific research and analytical instrumentation to the pharma industry. But it was BASi's CRO arm with facilities in West Lafayette and Evansville, Indiana, where they have bioanalysis, pharmacology, toxicology and in vivo facilities, that would form the basis for Inotiv.

## Stepwise and Strategic Build: Seventh Wave Laboratories

Established by former Pharmacia/Pfizer nonclinical scientists in 2003, Seventh Wave and BASi combined operations in 2018 to provide broader solutions and greater scientific expertise. Facilities in St. Louis and nearby Maryland Heights, Missouri, support a comprehensive portfolio of in vivo and analytical services focused on helping clients meet their goals, from optimizing the initial drug compound through regulatory-enabling studies. Seventh Wave Laboratories contributed GLP-compliant bioanalysis, pharmacokinetics, and histopathology services covering early discovery through regulatory approval. In vivo services focus on discovery stage support (in vivo pharmacology, exploratory pharmacokinetics, and toxicology) and feature unique pharmacology model development.

## Smithers Avanza Toxicology Services

In May 2019, BASi/Seventh Wave announced its acquisition of CRO Smithers Avanza's toxicology business unit in Gaithersburg, Maryland. This enabled even more specialized toxicology as well as vaccine safety and developmental and reproductive toxicology (DART) studies in support of pharmaceutical and chemical industry R&D. Not only has Smithers Avanza contributed a comprehensive portfolio of tools and services for drug safety and metabolism evaluations, but also experience in successfully defending clients' compounds during the approval and licensing processes. Other services this business unit added to help with the selection and optimization of drug candidates include in vivo toxicology and pharmacology, GLP in vivo

services, GLP and non-GLP/discovery bioanalysis, histology including immunochemistry and image analysis, drug metabolism, and pharmacokinetics.

## Pre-Clinical Research Services

In November 2019, BASi (Inotiv) acquired Ft. Collins, Colorado-based PCRS, a premier provider of surgical and medical device contract research services. This acquisition expanded the company's product development capabilities and provided surgical services for pharmaceutical and medical device clients.

## The Contributions of Each Added Entity Stack Up

Disciplines Needed	BASi	Seventh Wave	Smithers Avanza Toxicology	PCRS
In vivo in USDA-regulated species	●	●	●	●
Histology		●	●	
Pathology	●	●		
Bioanalytical chemistry	●	●	●	
Data analytics for pharmacokinetics		●	●	
Analytical chemistry/formulation analysis	●			
Pharmacology models		●		●
Toxicology	●	●	●	●
Developmental and reproductive toxicology			●	
Surgical capabilities				●
Imaging				●
Drug metabolism	●	●	●	●

## Becoming One

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The company has a core value of 'delivering excellent client experiences.' In order to deliver on that value, it was important to integrate the various services and truly become one company so the new name, Inotiv, was launched in November 2019. Early on, the company brought in a Senior Director of Business Process Excellence, Tammy Williams, to focus on integration and process harmonization. Soon after, the company recruited a Director of Program Management, Peggy Wyman, to support clients that place packages of work that span sites and disciplines. Most recently, a Client Experience department was formed, and Diane Francisco, Ph.D., was recruited to be the Senior Director of Client Experience. This group provides an interface between clients, business development, and laboratory operations to facilitate commercial interactions and on-boarding of new projects. Investments in harmonization and integration will continue into the future.

## The Outcome

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Over the past 18 months, Inotiv has undertaken significant internal and external growth initiatives to complement their cumulative assets. Investments in facility expansion and improvements, additional services, and hiring critical senior leadership and scientific talent provide a strong foundation.

Today, the company supports clinical decision-making with a comprehensive and integrated range of essential toxicology services, analysis, bioanalysis, drug metabolism, and consulting solutions.

For example, with deep expertise in assessing vaccine safety in early research, the Gaithersburg facility has been able to support several companies in need of rapid engagement to design, perform, and report on promising work in COVID-19 vaccine candidates.

Answering the right questions on time and with high-quality data is the key for drug developers to achieve their objectives and assess the promise of their drug candidates early on — and that's what Inotiv does best.

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## About Bioanalytical Systems, Inc., Operating as Inotiv

BASi, operating as Inotiv, is a pharmaceutical development company providing contract research services and monitoring instruments to emerging pharmaceutical companies and the world's leading drug development companies and medical research organizations. The Company focuses on developing innovative services supporting its clients' discovery and development objectives for improved decision-making and accelerated goal attainment. BASi's products focus on increasing efficiency, improving data, and reducing the cost of taking new drugs to market. Visit [inotivco.com](http://inotivco.com) for more information about BASi, operating as Inotiv.