

Birmingham Biotechnology Hub

- **Region:** Birmingham–Hoover MSA (Bibb, Blount, Chilton, Jefferson, St. Clair, and Shelby counties), with statewide connectivity through consortium
 - **Key Technology Focus Areas:** (1) Artificial intelligence, machine learning, autonomy, and related advances; (7) Biotechnology, medical technology, genomics, and synthetic biology
 - **Geographic Constraints:** Atlanta Regional Office, EPSCoR state, significant engagement and benefit to underrepresented communities
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Introduction

The frontiers of biotechnology, including the use of artificial intelligence (AI) for drug discovery and development and precision medicine, depend upon our ability to access, connect, and act upon large volumes of independent patient data. However, critical gaps in the data and its applications limit the potential of new technologies to improve health outcomes, particularly for communities disproportionately impacted by health disparities, such as Black and rural populations. Nearly 80% of genome-wide association studies globally are conducted on individuals of European descent, who comprise only 16% of the global population.¹ Similarly, non-White racial and ethnic groups are significantly underrepresented in U.S. clinical trials. For example, <20% of the drugs approved by the Food and Drug Administration (FDA) between 2014 and 2021 had clinical trial data addressing treatment benefits or side effects for Black patients. This lack of representation limits our understanding of the human genome, exacerbates generations of mistrust in medicine, and undermines the efficacy of treatments for underrepresented populations, further widening health disparities even as AI-driven precision medicine promises to better tailor diagnostics, therapeutics, and preventative care to patients' individual needs.²

The partners assembled in the Birmingham Biotechnology Hub recognize that we cannot truly unlock global competitiveness in AI-driven biotechnology and, by extension, a healthier and more economically productive America, without increasing representation in clinical genomic data and clinical trials. By leveraging AI in tandem with representative data, the Hub will become a global center of excellence in drug, vaccine, and diagnostics development. It will address the unique needs of underrepresented patient segments, improve diagnostic accuracy and drug efficacy, reduce timelines to develop new drugs and vaccines, enable rapid response to emerging health threats, and improve health outcomes of diverse patients at home and abroad.

Technology-based potential of the region for global competitiveness

Currently, over 90% of drug candidates fail to reach the market,³ and each successful candidate requires an investment of 10-15 years and over \$2B. AI is fueling a new drug discovery paradigm. In 2020, there were no AI-developed drug candidates in clinical trials. Today, there are 20+. These early successes are driving researchers, pharmaceutical companies, regulators, and payers to rapidly rethink the traditional drug development timeline,⁴ as evident in the passage of the 2022 FDA Modernization Act, which advances the use of technologies such as *in silico* analysis and AI modeling.

AI can identify new drug targets by finding patterns in large amounts of genetic and clinical data, evaluating and optimizing the properties of drug candidates to improve effectiveness and safety, predicting potential drug compounds' functional characteristics in patients, dissecting and stratifying patient populations into cohorts likely to have significant unmet drug discovery needs, and refining clinical trials and risk/benefit management of patients. Even modest improvements in early-stage drug development enabled by AI and machine learning (ML) could lead to an additional 50 novel therapies over the next 10 years—a \$50B opportunity.⁵ Researchers like Dr. Jake Chen⁶ and Dr.

Matt Might⁷ at the University of Alabama at Birmingham (UAB) are global opinion leaders on the intersection of AI and biotechnology, with nearly 300 total publications and presentations combined.

However, these new technologies are only as good as the data they are based on. Diversified genomic and clinical trial data are essential to power the computational models that will drive the transformation of drug discovery and development, clinical trial optimization, and disease prevention and diagnosis. The market with access to diverse patient data and the capability to assemble and utilize that data for commercialization will lead the next decade of computer-aided drug discovery. Birmingham is that market.

The Birmingham region has the density of existing assets, diverse patients, and pipeline of projects to accelerate the rate of drug discovery and development over the next ten years, leveraging the power of AI, trained with inclusive patient data, to shorten the drug development pipeline and deliver affordable drugs, vaccines, and diagnostics to effectively treat a diverse global patient population.

UAB, a Carnegie R1 research university ranked among the top young universities in the country,⁸ and Southern Research (SR), a nonprofit translational research institute specializing in drug and vaccine discovery and development, conduct over \$700M annually in research expenditures from grants in the biomedical sciences, placing Birmingham on par with MSAs such as San Diego, San Francisco, and Philadelphia on a per-capita basis. UAB and SR are national research leaders in oncology, infectious disease, precision medicine, and population health. Sponsored research at UAB has surged in recent years, growing 31% year over year, including ~\$120M annually in clinical trials, ranking it fourth in annual research spending growth nationally. Since its founding in 1941, SR has developed seven FDA-approved cancer drugs, including two on the World Health Organization's list of essential medicines, and has tested half of the active chemotherapies available in the U.S.

Together, UAB and SR are investing in accelerating the Birmingham region's translational capabilities, with ~\$640M in new research facilities expected to come online by 2025, supported by ~\$90M in state and local funding. UAB is building a \$78M, 175K sq. ft. **Genomic Medicine and Data Sciences Building** to accelerate research, translation, and commercialization in genomic medicine and computational biology by co-locating researchers and translational scientists, equipment, and staff from the Precision Medicine Institute, the Informatics Institute, and the Harbert Institute for Innovation and Entrepreneurship (HIIE). The project will attract \$100M in additional research funding annually. The University also received \$152M in federal funding to construct a new **Biomedical Research and Psychology Building**. These assets complement UAB's core facilities, including the **UAB Cyclotron Facility** and **Cheaha Supercomputer**.

Leveraging these and other assets and investments, combined with Tech Hub designation and implementation support, the Hub will drive high growth within critical subsectors of the global biotech market, including AI-enabled drug discovery (\$50B+ by 2033),⁹ contract R&D (\$103B by 2033, 7.8% CAGR),¹⁰ clinical trials (\$93B by 2033, 5.8% CAGR),¹¹ and diagnostics (\$448B, 8.6% CAGR).¹² These subsectors alone are expected to create a nearly ~\$700B market by 2033. Our Hub has the potential to capture meaningful shares, particularly in fast-growing areas such as AI-enabled drug discovery. Capturing between 0.5% (diagnostics) and 2.5% (AI-enabled drug discovery) share of these subsectors would give Birmingham ~1% of the total global market, ~\$7B in 2033.

Innovative "lab to market" approaches

State and local partners have collaborated for decades to develop the Birmingham biotech ecosystem. For 35 years, Innovation Depot (Depot) has incubated and accelerated tech- and bio-focused, high-growth businesses like publicly traded IN8bio and Therapy Brands (sold to KKR for \$1.25B in 2021). Since 2006, the Economic Development Partnership of Alabama (EDPA) has

invested in 114 companies now valued at \$1B through **Alabama Launchpad**. Innovate Alabama and BIO Alabama marshal federal and state incentives and investments to biotech companies, like the **Supplemental Grant Program** for companies with an active Phase I or II Federal Small Business Innovation Research Program or Federal Small Business Technology Transfer Program grant. Companies may apply for a 50% match of up to \$100,000 for Phase I awards, and \$250,000 for Phase II awards. Meanwhile, local venture firm First Avenue Ventures conducts a Life Sciences fund dedicated to early-stage Alabama companies like Alveolus Bio and TriAltus Bioscience.

SR is the commercialization engine for over 150 commercial and academic partners, including UAB, carrying early-stage drugs through to Phase 1 clinical trials. SR is bridging the “Valley of Death” through investments in **Station 41**, a biotech commercialization hub that supports three programs designed to assist firms at all stages of development. The **Accelerator** provides non-dilutive funding up to \$100K per program to advance new drugs, biologics, or diagnostic products. The **Incubator** offers 15K sq. ft. of leasable wet lab and office space, shared lab equipment, and services like hands-on mentorship and advising. The **Venture Studio** works with licensing partners to advance products with non-dilutive and equity funding. Additionally, SR and UAB are launching **Venn Labs** in 2024, a CLIA-certified research and reference diagnostic lab that will provide a platform for rapid creation and deployment of lab-developed tests.

UAB’s HIIIE is an essential partner to SR in translating basic research to startup potential. HIIIE is pioneering a one-of-a-kind **biotechnology Ph.D. program** that is launching this Fall to provide students with the technical and executive skills required to launch a successful biotech company. HIIIE also advocates for policies to catalyze commercialization. The University of Alabama system and the UAB Office of the Provost are reviewing recommendations to broaden evaluation criteria for **faculty tenure consideration** to include patents, commercialization outcomes, and participation in related economic development initiatives.

SR, UAB, and Tuskegee University are members of the UAB **CCTS Partner Network**, which includes 11 academic institutions spanning Louisiana, Mississippi, and Alabama. This regional network has created extraordinary translational capacity by establishing both a platform for multi-institutional collaboration and the underlying institutional commitments to translational science and fundamental and clinical research. It is one of approximately 50 Clinical and Translational Science Awards (CTSA) programs nationwide, and the only one in the Deep South.

Equity & diversity

The patient data at the foundation of the Hub’s innovative potential will be sourced from points of care ranging from rural pharmacies to cutting edge cancer centers and patients spanning social determinants of health (e.g., geography, income, education, race and ethnicity, and family history). To assemble that data, we will draw on existing strengths in patient recruitment and work to increase participation of Black researchers, clinicians, entrepreneurs, investors, students, and workers at every step of the concept-to-clinic journey, building on talent pipeline development lessons from the region’s American Rescue Plan Act **Good Jobs Challenge** grant, led by the City of Birmingham.

UAB’s genomic database contains more data from patients of racially diverse populations than all other global data banks combined. It is built on decades of work by Dr. Mona Fouad and the **Minority Health & Health Equity Research Center** (MHERC), which provides researchers with diverse recruitment services and links to community-based organizations, providers, and participants. In the past five years, MHERC and its partners have enrolled 31K+ participants in 14 studies, including over 6K+ participants for the **Alabama Genomic Health Initiative** (AGHI) and ~24K participants for the federal **All of Us** project, including >40% of recruits from racially diverse populations. Industry also recognizes Hub partners’ strengths in recruiting diverse patient

populations. In 2021, Genentech recruited UAB as one of four founding partners in its **Advancing Inclusive Research® Site Alliance** to diversify patient populations in oncology clinical trials.¹³

SR is currently developing a genomic data and clinical trial network called the **Catalyst Project** (Catalyst), with the goal of sequencing 100K Alabamians' genomes by 2026—and with a focus on racially diverse and rural populations. Catalyst will provide pharmacogenomics, disease risk estimates, and early disease diagnoses for enrollees. Enrollment will include consent to be contacted for participation in clinical trials, enabling more precise matching of trials to specific patient groups based on their genetic and clinical profiles. Paired with Venn Labs, Catalyst will better equip practitioners to intervene at the point of primary care to reduce risk factors and bring precision medicine to patients previously disconnected from such innovations, especially underinsured, Black, and rural patients. At full potential, Catalyst will create an additional 1,200 jobs in rural Alabama.

The Hub also includes Acclinate, a Black-owned company headquartered in Birmingham that uses predictive analytics and machine learning to source diverse leads who are likely to participate in clinical trials, reducing recruitment time and costs while measurably increasing participation from communities of color. Acclinate is an EDPA Alabama Launchpad winner, a clinical trial recruitment partner for Catalyst, and works closely with UAB's MHERC. Through programs like **Bridging the Gap**, which fosters community dialogue about AI/ML in healthcare, Acclinate, and Hub partners aim to ensure communities of color actively participate in developing healthcare technologies.

Given the Hub's goal to address a long history of racial inequality in the history of medical research and health care, the participation of Historically Black Colleges and Universities (HBCUs) is essential to our success. For example, Tuskegee boasts some of the nation's leading experts in bioethics and health disparities as well as the country's **National Center for Bioethics in Research and Health Care**. Additionally, Lawson State Community College, Miles College, and Tuskegee University frequently collaborate with other Hub partners in research, talent development, and patient recruitment projects. As the state with the most HBCUs, Hub partners are determined to grow opportunities for HBCU students, researchers, and alums, as detailed in commitment letters.

Composition and capacity of the regional workforce & the role of the private sector

Today the Birmingham MSA is home to ~4,553 biotech jobs. Assuming an annual growth rate of 7.4%,¹⁴ we can reasonably expect the Hub to **generate ~36K new jobs** over the next decade, **including ~9K direct jobs and ~27K indirect and induced jobs**. By 2033, these new jobs could generate an **incremental \$2.35B in wages** for Birmingham MSA residents.

Achieving these ambitious targets will require Hub partners to close some known gaps such as: growing entry-level biotech talent, growing and attracting mid- and senior-level biotech talent, effectively connecting qualified talent to available jobs, creating more wet lab space, and matching emerging biotech startups to equity capital. Successful biotech companies like Evonik and Avanti Polar Lipids are already working with AIDT to develop early-career talent in the biotech industry through a three-phase **bioscience training program** that prepares job seekers for entry-level work and will lead to a sustainable career in biotechnology. Priority occupations for training and placement include phlebotomists, clinical laboratory technologists, biological technicians, medical scientists, and genetic counselors. These job categories grew 43% between 2017 and 2022 and generate average wages of ≥\$23.64 per hour,¹⁵ well above the living wage of \$16.55 for a household with one adult and no children in the MSA.¹⁶ These jobs will provide improved wages with low barriers to entry (e.g., requiring no previous work experience and only a high school diploma or non-degree credential).

Meanwhile, EDPA is working to retain and match the surplus of biomedical sciences graduates from Alabama universities,¹⁷ especially HBCUs, with employer demand through **Retain Alabama**. UAB is working to define credit schemes for accessing programs like their biotechnology Ph.D. or

M.S. in genetic counseling and has developed an asynchronous online certification for genomic variant analysts to increase accessibility of clinical genomics jobs for incumbent and non-degreed workers. Hub partners are committed to developing workforce pipelines for unemployed and underemployed job seekers and incumbent workers at every rung of the biotech career ladder. These partners are also committed to clustering workforce training and jobs through place-based investments in Birmingham, such as the envisioned **Southtown Biotech Innovation District**: a development project led by the Housing Authority of Birmingham District and Corporate Realty.

Regional coordination & partnerships

Hub partners have a proven record of collaborating to boost regional innovation and workforce development. The Hub will operate as an equal partnership that ensures full participation, input, and equal opportunities for all members. While aiming for consensus, an odd number of voting members will decide when needed. SR will lead the Hub following this preliminary structure:

- A **steering committee** with a representative from each Hub member to shape and implement the Hub strategy. The RIO will be hired by SR, with committee representatives on the hiring panel. Seven of the 13 steering committee member organizations are Black-led.
- A broader group of **advisors**, separate from the steering committee, and informed about key developments and tapped for insights and participation.
- **Working groups**, consisting of steering committee members and advisors, to drive inclusive implementation. Potential projects may include commercialization and workforce development programs for racially diverse researchers and founders, creation of additional incubator, accelerator, and wet lab spaces, and a workforce training facility complete with wraparound services.

Conclusion: Impact on economic and national security of the United States

Over the last decade, China has rapidly increased its investment in the biotech industry with the goal of “own[ing] the biorevolution.”¹⁸ It has made the expansion of gene banks a strategic priority and is aggressively trying to secure access to and control over individuals’ biomedical data. But while China has the benefit of a large volume of data (allegedly ~600M+ genomes), it lacks the population diversity of the United States. Leveraged effectively, this diversity could be a strategic advantage.¹⁹

As we emerge from a global coronavirus pandemic and anticipate the U.S. population shifting to majority non-White by 2045,²⁰ increased diversity in clinical genomic data and clinical trials is necessary for our pandemic readiness and national security in the face of future disease threats. Massive government and commercial investment went into the response effort to the COVID-19 pandemic. The process revealed significant gaps in our ability to quickly develop and approve diagnostics and treatments.²¹ The same *in silico* computational and AI technologies used to improve commercial drugs can position us to respond rapidly to emerging health threats.

The pandemic also exposed the human cost associated with widespread chronic disease. Chronic diseases are the leading cause of disability and main driver of the nation’s \$4.1T annual healthcare costs.²² If just 1% of health disparities were alleviated by improved diversity in clinical trials, the U.S. economy would see \$40B-\$60B in gains for diabetes and heart disease, which disproportionately affect the nation’s Black population,²³ who also accounted for nearly 24% of age-adjusted COVID deaths in the United States.²⁴

Catalyzing the Birmingham region as a global center of excellence in drug, vaccine, and diagnostics development will increase our national preparedness to meet global health threats while reducing development timelines and addressing the unique needs of underrepresented patients.