

Novi Systems
Fusion Analytics for Rare Diseases

A Letter from the CEO & Founder

I'm pleased to announce the commercial launch of our "Fusion Analytics platform" to further empower users to solve complex problems in healthcare and the bio/pharma industry. Thanks to our colleagues at Thermo Fisher, one of the largest global contract-manufacturing companies, we have successfully validated *Regulatory Compliance for Biomanufacturing*, which is now available to be licensed as a combined hardware/software package.

Our Novi Systems team of engineers and developers has also made significant progress in developing the *Rare Disease Integrator*. We are looking for collaborators to help us validate it in hospital systems, specialty clinics, and children's hospitals. Our patient-centric *Rare Disease Integrator* draws from multiple sources—e.g., medical, regulatory, billing, and payer databases—to ensure that clinical teams can provide patients and their families with the best diagnostic, treatment, and resource solutions for rare genetic diseases and genomic-characterized cancers. Patient advocacy organizations, such as Taylor's Tale and the NC Patient Coalition, have guided development of the *Rare Disease Careway*, which enables patients/families to gain direct access to relevant, integrated information and resources for their challenging journeys.

As an immunologist and business executive, I helped to launch the biotech industry with a major focus on rare diseases, i.e., U.S. patient groups under 200,000 as determined by the FDA. While serving as senior VP for Biogen Idec and Pfizer vaccines/biotech (formerly Wyeth), I grew increasingly frustrated with the inability of our IT vendors and in-house staff to integrate data between various systems so we could optimize business operations across multiple domains. Retiring early, I decided to focus on developing public-private partnerships to improve operational efficiencies and ensure that hospital and industry operations functioned in a high state of control and regulatory compliance while further meeting the needs of patients.

I joined the faculty at North Carolina State University, which is a recognized leader in engineering and computer science, and became Director of the Institute for Next Generation IT Systems. Along with Technical Director John Bass and a team of fusion-analytics developers, I collaborated on innovative software projects with IBM (including the Watson Jeopardy initiative), healthcare industry, and government agencies. During that time, we helped to obtain one of the largest translational research grants ever awarded by the University of North Carolina's network of universities and colleges. It was a patient-centric grant that enabled us to create a "Rare Disease InfoHub" as we explored how analytics and AI techniques could specifically support the rare disease community.

One of our observations was that "IT vendors often focus on creating solutions that attempt to replace highly skilled personnel with systems ... instead of creating systems to equip skilled personnel to accomplish their tasks." We also concluded that, to capture maximal value for rare disease patients and healthcare teams, we had to spin off the *Rare Disease Careway* into a company.

John Bass and I thus formed Novi Systems in 2018 with a primary objective to accelerate development of “real world” data integration solutions as well as to keep people in control of the analytics. Our team has created a broad-based platform that abstracts the complexity of Natural Language Processing and Machine Learning techniques to empower users as they generate actionable answers from complex data without being data scientists. They can therefore focus on the problem and not the technology.

We look forward to applying our innovations in fusion analytics not only to rare diseases and genomic-characterized cancers but to all facets of business operations and clinical medicine within health systems—while always keeping the patients and families at the center of our mission.

Thanks for your consideration,

Dr. Michael Kowolenko
CEO & Founder
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