

IASO

THE PATIENT JOURNEY WITH IASO

Collaborative Innovation

Therapeutics Design & Development

Device Design & Development

Enterprise Operational Excellence

Clinical Development

Manufacturing Excellence

Commercialization



IASO

On average, Life Sciences companies spend \$1 billion over 10 years to bring a new therapeutic to market. The most innovative among them are turning to novel formulation strategies and delivery systems that can vastly improve the patient experience—the next frontier in drug development.

Biologic drugs have become a driving force in the Life Sciences industry to treat complex diseases; however, special delivery systems are often required, keeping patients at the clinic for long periods of time. Demands for greater patient autonomy are causing companies to rethink how they can enable patients to self-administer the drug in the comfort of their own homes.

Nowhere is innovation to enhance the patient experience more critical than with these novel large molecules and the required mechanisms to deliver them. Thus, high-tech large-volume wearable injectors in the form of combination products are sure to play a critical role in the future success of these new therapeutics by shifting the point-of-care from hospitals and clinics to the patients' homes.

IASO, named after the Greek goddess of recovery, is a Life Sciences showcase for the lifecycle of a combination product in oncology. From upstream thinking through to commercialization, **IASO** demonstrates the value that Dassault Systèmes and the **3DEXPERIENCE** platform can deliver to stakeholders challenged with bringing innovation to market in the form of combination products that transform the patient experience.



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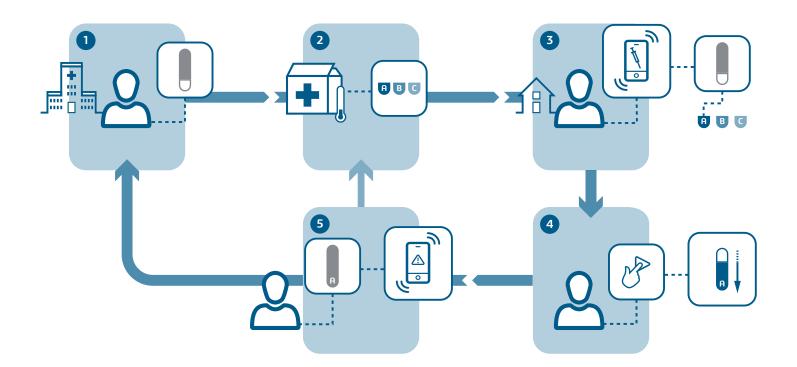
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THE PATIENT JOURNEY WITH IASO



- 1 The patient comes out of the hospital with a patch installed on their arm for three main purposes:
 - To secure the catheter that has been positioned inside the vein which will be used for the IV injection of a drug.
 - To attach the injector + cartridge when the treatment needs to be administered.
 - To monitor the efficacy of the treatment in real time + collect and analyze data to generate analytics.
- 2 The patient will receive a refrigerated box that contains the injector + the different drug cartridges at home via digital prescription.

- 3 When the patient is notified through their mobile phone to proceed with the injection, they will lock the injector and the appropriate cartridge together, and then plug in the combination product on the patch that is fixed to their arm.
- 4 The patient will then press the Play button on the **IASO** screen to launch the injection of the biologic therapy.
- **5** Once the injection is over, the **IASO** screen will inform the patient. The patient will then unplug the injector from the patch and store it for the next injection.

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The interest in biologic drugs has risen in recent years due to their superior efficacy, safety, pricing, exclusivity—and most importantly—the ability to satisfy previously unmet medical needs.

In order to be competitive, companies have to reinvent their the delivery of these much needed therapeutics and must take into consideration input from not only all stakeholders within the company, but also external voices in research, industry, the clinic and of course, the patient.

The Collaborative Innovation tools on the **3DEXPERIENCE** platform make the ideation steps for drug and device social through a global network of partners, from market intelligence to early prototyping and validation. Target product profiles can be defined quickly in the upstream discovery phase and corroborated by real-time data insights and clinical feedback to drive more-informed decisions. The best ideas are seamlessly promoted to requirements to quickly arrive at the best combination product design.

BENEFITS OF USING THE 3DEXPERIENCE **PLATFORM FOR COLLABORATIVE INNOVATION**

- · Improve your innovation process
- Accelerate your concept design
- Reduce project management overhead
- Extended scientific collaboration across network.

Discover our Industry Solutions:

- Collaborative Scientific Innovation
- Empowered Design Innovation

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THERAPEUTICS DESIGN & DEVELOPMENT

The focus of drug discovery and development has gradually shifted away from small, well-defined chemical molecules to large, complex molecular entities called therapeutic biologics. These biotherapeutics are now playing an increasingly prominent role in combating cancer, diabetes and autoimmune diseases.

The fundamental challenge facing the Life Sciences industry is how to optimize R&D efficiency and productivity for these biotherapeutics from early-stage discovery to commercial manufacturing. To reduce time and costs in R&D, there is a growing focus—especially during early-phase discovery and development—toward earlier decision making to identify quality therapeutic candidates and ensure the lower quality candidates "fail early".

Therapeutics Design and Development delivers collaborative, knowledgedriven innovation, and predictive analytics to address these challenges.

BENEFITS OF USING THE 3DEXPERIENCE PLATFORM FOR THERAPEUTICS DESIGN & DEVELOPMENT

- Unify cross-discipline teams seamlessly
- · Deepen analysis and improve decision making
- Improve success rate of therapeutic targets
- Increase market exclusivity

Discover:

- ONE Lab
- Designed to Cure



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The delivery of new and novel biologic therapeutics to patients is complicated as the formulation can be viscous and must be delivered in large volumes. Devices used to administer these drugs also have to be easy to use, yet safe and efficacious to meet regulatory and patient approval. Thus, rigorous testing of the design during the Device Design and Development phase is critical to meet all standards, and the bottom line.

Best in class modeling and simulation tools on the **3DEXPERIENCE** platform integrate designers and engineers allowing them to assess the performance and safety of smart, connected medical devices and rapidly explore device and patient variability to optimize device performance for individuals.

BENEFITS OF USING THE 3DEXPERIENCE PLATFORM FOR DEVICE DESIGN & DEVELOPMENT

- Reduced cycle times
- Accelerated design and development processes
- Improved productivity
- Fewer cost of design errors
- · Lowered cost of quality

Discover our Industry Solutions:

Engineered to Cure

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ENTERPRISE OPERATIONAL EXCELLENCE

Product information for a combination product is managed through highly fragmented processes and systems. Companies who have not embraced digitalization, run the risk of non-compliance with regulatory standards, inferior product quality, and inefficient project execution. A simple change can wreak havoc on paper-based organizations, resulting in a loss of time and money.

To achieve quality that positively impacts the organization, Life Science companies need to take a holistic end-to-end approach to the product lifecycle. The **3DEXPERIENCE** platform infuses digital continuity and powerful PLM analytics to integrate design activities in a single referential with unified change management and a seamless link to project management and design review which is critical in the context of a combination product such as **IASO**.

BENEFITS OF USING THE 3DEXPERIENCE PLATFORM FOR ENTERPRISE OPERATIONAL EXCELLENCE

- Global closed-loop process and project management
- Greater traceability and control of changes
- Change impact assessment: "Where-used" capabilities
- Improved collaboration and assignment of dedicated stakeholders and experts
- Unified dashboard-driven view of change-related information

Discover:

- License to Cure for Biopharma
- <u>License to Cure for Medical Device</u>

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THE 3DEXPERIENCE®
PLATFORM ADVANTAGE

CLINICAL DEVELOPMENT

Before a combination product can reach the market, rigorous clinical research and testing is required to ensure the treatment safety and efficiency for all patients.

The Dassault Systèmes Medidata Brand offers game-changing patient-centric solutions to conduct **IASO** clinical trials from start to finish. With the help of Acorn Al's Trial Design solution, a robust clinical trial program can be designed using Clinical Trial and Real World Data. Confidently identify target populations, select controls or comparators, assess risk:benefit ratios, and inform Go vs. No-Go decisions.

The MyMedidata Patient Portal puts the patient at the center of the process and also addresses the dilemma of accruing and retaining patients while navigating trial virtualization. Clinical trial study staff and patients are directly connected, facilitating the transmission of consent, data and patient feedback.

BENEFITS OF USING MEDIDATA FOR CLINICAL DEVELOPMENT

- · Optimize your trials with the largest dataset in the world
- Reduce complexity and risk for all your data and processes
- Streamline your study workflow and improve productivity
- Streamline operations with an end-to-end clinical process
- Run patient-centric studies sponsored by MyMedidata

Discover:

- Medidata Acorn Al
- Medidata Rave EDC
- myMedidata

MANUFACTURING EXCELLENCE

Increasing development costs, shifting outcome-based economic models, and ever-evolving global compliance needs are forcing companies to completely realign their offerings, processes, supply chains, and business structures to facilitate innovation, agility and sustainable, high quality output.

Connecting people with information and data ensures Manufacturing Excellence and enables quicker, more informed decisions. Infusing virtualization and simulation into manufacturing planning and operations helps ensure therapies are produced 'As designed' and 'As registered' in the most cost-effective and high-quality manner.

BENEFITS OF USING THE 3DEXPERIENCE **PLATFORM FOR MANUFACTURING EXCELLENCE**

- Virtually experience the entire process, from factory design to production
- Achieve real-time visibility, control and synchronization of business processes spanning global operations
- Extract real-time manufacturing intelligence to support global continuous process improvement

Discover our Industry Solutions:

- Made to Cure for Biopharma
- Made to Cure for Medical Device



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Understanding the product's clinical benefits and challenges, the patient and patient journey, and how to position it with healthcare professionals and payers are critical to building a sound commercial strategy. And at the core of that strategy is having the right data and insights to size the market opportunity, build a brand strategy, find patients, initiate therapy, and maximize medication adherence.

Medidata Acorn Al's commercial data management technology and advanced analytics provides a 360-degree view into the performance of the product from day one, ensuring the right patient gets the right treatment at the right time.

BENEFITS OF USING THE 3DEXPERIENCE PLATFORM FOR COMMERCIALIZATION

- · Plan a brand launch with confidence
- · Develop sales strategies with clarity
- Manage commercial operations with certainty
- Accelerate time to peak performance

Discover our Industry Solutions:

• Medidata Acorn AI Commercial Data Solutions

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THE 3DEXPERIENCE®
PLATFORM ADVANTAGE

THE 3DEXPERIENCE® **PLATFORM ADVANTAGE**

The global biologics market is predicted to surpass \$456.83B by 2027 due to a rise in the regulatory approval of biologic drugs. These novel biologic solutions, dosed with connected, wearable and reusable delivery devices, are transforming the patient experience by shifting the point-of-care from clinics to the patient's home.

To capture the market and leapfrog the competition, life science companies who are embracing these industry trends must adopt a comprehensive global approach to quality, regulation and compliance. A unified quality solution provides a single source of truth, ensuring enterprise-wide data integrity, consistency and reliability.

The Dassault Systèmes **3DEXPERIENCE** platform connects all people, processes and data among disciplines including Research, Development, Process Engineering, Quality Compliance, Regulatory Affairs, Manufacturing and Commercialization.

This business experience platform ensures that Product Lifecycle Management will not be just another disparate application or viewed as a limited or incomplete solution; rather, it will demonstrate how to deliver collaborative innovation and operational excellence through complete digital continuity.

Learn More:

https://ifwe.3ds.com/life-sciences

Our **3D**EXPERIENCE® platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3DEXPERIENCE** Company, is a catalyst for human progress. We provide business and people with collaborative virtual environments to imagine sustainable innovations. By creating 'virtual experience twins' of the real world with our **3DEXPERIENCE** platform and applications, our customers push the boundaries of innovation, learning and production.

Dassault Systèmes' 20,000 employees are bringing value to more than 270,000 customers of all sizes, in all industries, in more than 140 countries. For more information, visit **www.3ds.com**.



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