DASSAULT SYSTEMES

CLINICAL DEVELOPMENT TO PROTECT

ACCELERATE CLINICAL DEVELOPMENT TO BETTER PROTECT POPULATIONS

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EXECUTIVE SUMMARY

As the world focuses its efforts on continued research for diagnostics, treatments and vaccines for SARS-CoV-2, many governments are looking for ways to strengthen their medical & scientific research capabilities and create a stronger foundation to deliver these vaccines and cutting-edge therapeutics, as well as establish a foundation of collaborative research in preparation for the next crisis.

Governments, health ministries, agencies, research institutions and partner companies around the world are understanding that in order to meet these challenges they must excel in scientific leadership and transform the processes throughout their highly-networked ecosystem.

OUR UNDERSTANDING

The COVID-19 pandemic crisis has convinced the world of the necessity to rapidly develop innovative, safe, and well-coordinated national medical emergency responses to prevent or quickly mitigate other devastating pandemics in the future.

The fundamental challenge facing organizations who focus on the innovation of treatments for novel diseases is how to optimize their medical research efficiency and effectiveness.

The future of global public health is dependent on the scientific and medical communities' ability to develop readily available, accurate, and rapid virus and antibody tests and to discover highly effective vaccines to further prevent spread of the virus as well as mitigate the likelihood that it will reappear.

HOW DASSAULT SYSTÈMES CAN HELP

Dassault Systèmes provides sophisticated scientific solutions to allow government agencies and public medical research Institutions to manage their innovation life cycle. We provide these institutions & their researchers with a medical, scientific and business platform to imagine sustainable innovations, capable of improving patient & physician experiences in the age of precision medicine.

With over 30 years of investment in Life Sciences and Healthcare solutions, Dassault Systèmes has developed a scientifically enabled technology platform to allow public Health Ministries and Departments, and their underlying Medical Research Agencies, to digitize scientific knowledge and workflows from discovery to development and on to patient access. The ability to connect the dots across the innovation continuum and connect the people and knowledge of organizations on a platform with deep science is our differentiation.

Dassault Systèmes' Medidata has solutions that can be immediately leveraged by our biopharmaceutical and Contract Research Organization (CRO) clients to both better understand the impact of the pandemic on their trials and to mitigate the challenges of patients unable to visit sites for their drugs and protocol-directed clinical and patient-reported data capture.

Worldwide, we have partnered with many entities in the public and academic sector (e.g. **US FDA, NIH, Harvard, MIT, UCSF, Imperial College London, Cambridge University, Cancer Research UK, Genopole, INSERM, Université de Strasbourg, FAU Erlangen Universität, Shanghai Jiao Tong University, Curtin University**) as well as private sector companies to accelerate their scientific discovery and medical research in biology, chemistry and materials science by leveraging our deep scientific knowledge, technology solutions and services.

We are prepared to offer our support in defining the most efficient approach to solve these complex medical research challenges, in order to accelerate the discovery and delivery of critical life saving solutions.

OUR UNDERSTANDING

GLOBAL INNOVATION CHALLENGES

Medical research institutions look for solutions that can be immediately leveraged to both better understand the impact of the COVID-19 pandemic on their trials, and to mitigate the challenges of patients and monitors unable to visit sites.

Strategic Objectives of Trial Sponsors and CROs

Understand the Envolving Situation

- **Study/sponsor level metrics and dashboards to better understand impact on enrollment, patient visits, data collection, query response rates, and additional metrics to help diagnose risk areas**
- **Industry-wide dashboards and analysis to understand trends globally and areas of greater or lesser**

Reconsider Trial Design for Data Capture

- **Increased study virtualization to reduce patient visits and minimize site burden**
- **Shift site mix to lower-impacted countries/regions**
- **Consider synthetic controls to reduce patient enrollment needs**

Maintain Supply & Quality

- **Centralize data oversight and monitoring activities, bringing identification of patient anomalies earlier in the process and away from onsite identification**
- **Closely monitor patient volume and drug supply to minimize supply disruptions**

Accelerate Study Startup

- **Safely and effectively accelerate study start up times through faster investigator budgeting, so cures and treatments can get to market faster**

HOW DASSAULT SYSTÈMES CAN HELP?

POTENTIAL OPPORTUNITIES FOR PUBLIC MEDICAL RESEARCH INSTITUTIONS

Public research institutions can realize significant scientific and operational value while delivering consequential patient impact by adopting Dassault Systèmes MEDIDATA solutions to support trial challenges. Outcomes are achieved by leveraging the global digital continuum to accelerate innovation, improve collaboration and enhance discovery.

UNDERSTAND THE EVOLVING SITUATION

Trial Impact Analytics provides COVID-19 tracking and forecasting powered by 6,000 active and 20,000 overall industry trials.

Real-Time Situation Tracking informs critical decisions by monitoring the impact of COVID-19 on enrollment, data collection and visits and provides standard reports to track impact of COVID-19 for customer and across the industry, trends and YoY comparisons, updated weekly and views at the study, portfolio, country, region, and site level

Impact Forecasting tracks leading indicators of slowdown and recovery for planning, overlay trends in COVID-19 testing and infection rates with impact on trials and identify markers of recovery at a country and region level.

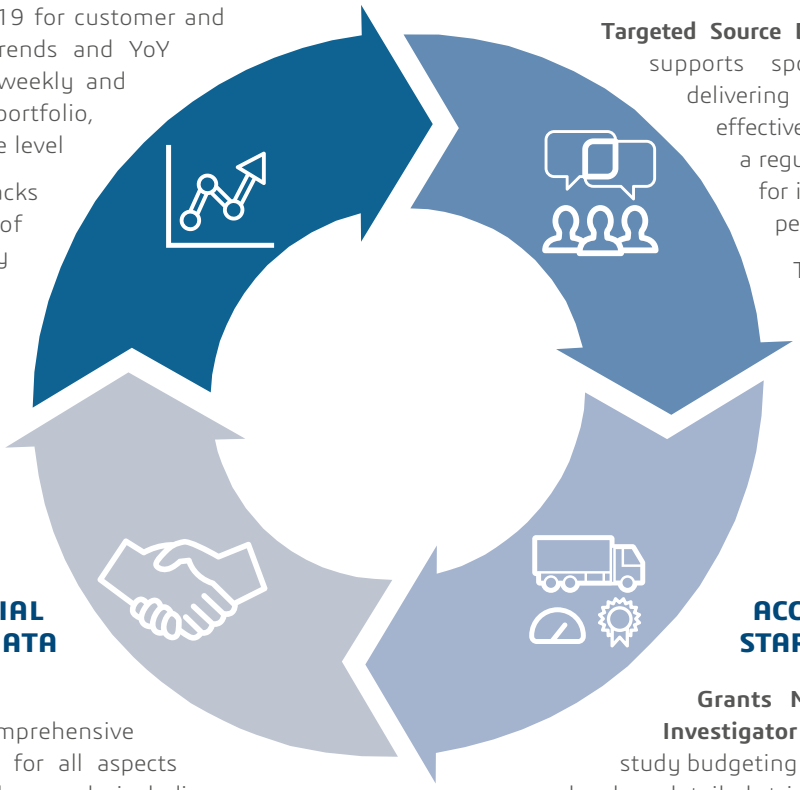
MAINTAIN SUPPLY QUALITY

Risk assessment guidance & template and Medidata Detect to support sponsor oversight responsibilities with next-generation analytical tools and algorithms (<2 weeks go-live).

Remote Source Review can assist in the SDV / SDR process and support critical document acquisition / review due to limited site access.

Targeted Source Data Verification (TSDV) supports sponsors and CROs in delivering quality data in a time effective and cost-efficient using a regulatory supported method for identifying critical data to perform reduced SDV.

Through **RTSM** sites can process drug dispensation through EDC as a visit and send the drug directly to the patient via a courier.



RECONSIDER TRIAL DESIGN FOR DATA CAPTURE

myMedidata is a comprehensive patient-centric tool set for all aspects of site-based and virtual research, including a COVID-19 symptom tracker that can be used as a registry.

eCOA can convert site-based data forms to remote data forms. Remote consent supports virtual patient enrollment.

Synthetic Controls leverage historical clinical trial data to augment or replace control arms of trials to the next phase, reduce patient enrollment burden or increase statistical power. that are in danger of high dropout or unfulfilled enrollment due to COVID-19; reduce scientific uncertainty to advance.

Coder includes the updated MedDRA 23.0 dictionary with new COVID-19 terms and revisions.

ACCELERATE STUDY STARTUP

Grants Manager for COVID-19 Investigator Initiated Studies is a study budgeting solution that can quickly develop detailed trial budgets for patient, procedure and site costs.

RTSM with **EDC** forms can go live in as little as 2-3 weeks.

HOW DASSAULT SYSTÈMES CAN HELP?

DASSAULT SYSTÈMES SOLUTIONS: CATALYZING TRANSFORMATION THROUGH SCIENCE

Understand the Evolving Situation trough Trial Impact Analytics

- Study / sponsor level metrics and dashboards to understand impact on enrollment, patient visits, data collection, query response rates, and additional metrics to help diagnose risk areas
- Industry-wide dashboards and analysis to understand trends and compare areas of disruption
- Impact forecasting to overlay trends in COVID-19 testing and infection rates with impact on trials to understand leading indicators of slowdown and identify markers of recovery

Reconsider Trial Design for Data Capture through myMedidata and Synthetic Controls

- Increased study virtualization to reduce patient visits and minimize site burden. Any Rave EDC study using eCOA can have additional data forms pulled into the eCOA app for patients
- Synthetic Controls to reduce patient enrollment needs: Support research by providing aggregated data to support understanding of AEs. Leverage historical clinical trial data to augment or replace control arms of trials that are in danger of high dropout/unfulfilled enrollment

Maintain Supply & Quality through RTSM and RBQM based Virtual Monitoring

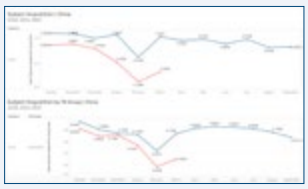
- Monitoring of patient volume and drug supply to minimize supply disruptions
- Adjustment of supply plan to ensure that the site is stocked with additional drug, such as calculating drug needed for additional visits
- Risk assessment, remote monitoring & centralization of data oversight and monitoring activities, bringing identification of patient anomalies earlier in the process and away from onsite identification

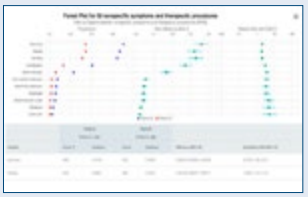
Accelerate Study Startup through Grants Manager

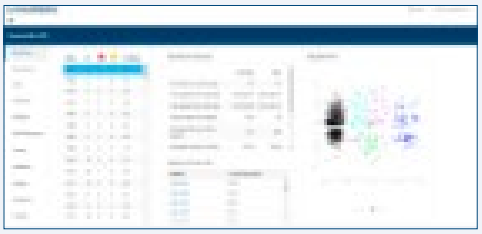
- Budgeting assistance to enable sponsors focused on developing vaccines against, and treatments for COVID-19 to safely and effectively accelerate study start up times through faster investigator budgeting, so cures and treatments can get to market faster
- Deep fair market value data that supports auditable, defensible rates and a study complexity analyzer to calculate benchmarks with industry averages, along with a site's work effort, to help sponsors determine fair site payments

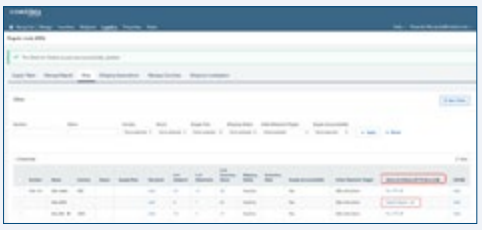
We believe there is significant opportunity to facilitate key objectives in therapeutic diagnostic and treatment design for public research institutions by leveraging predictive science, reducing time to target and candidate identification, and simplifying access to information through improved collaboration across organizations.

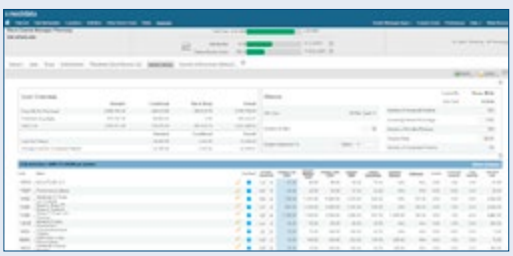
We see further substantial opportunities for increased efficiency and accelerated research timelines by implementing a collaborative framework that standardizes and streamlines scientific operations.





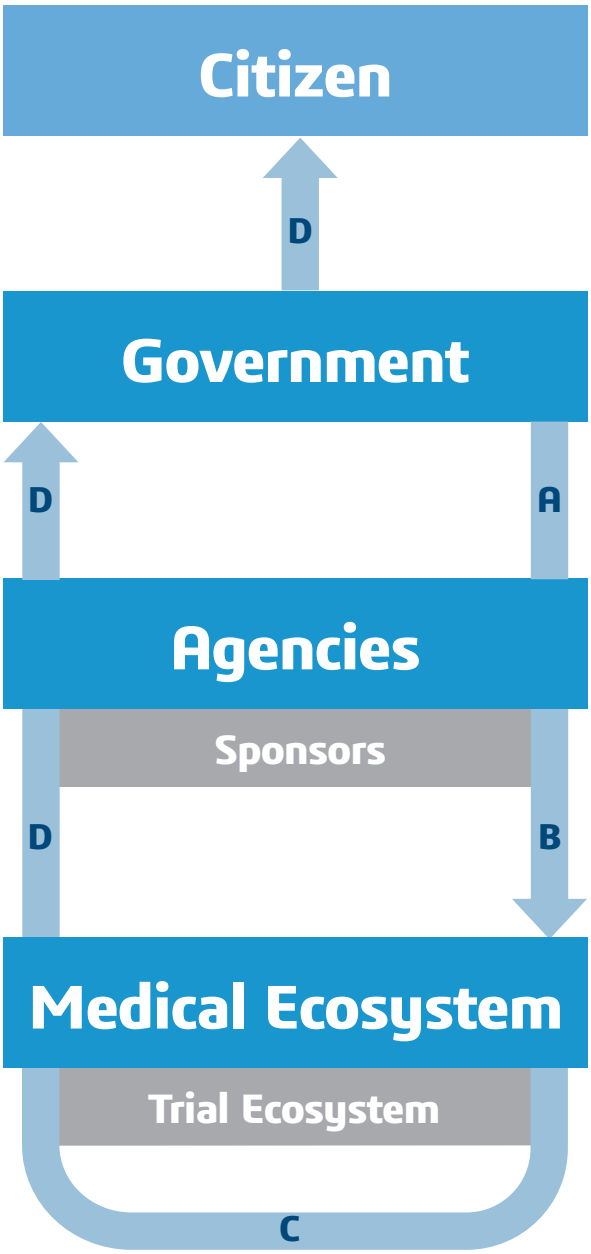






CASE FOR CHANGE

STRATEGIC BENEFITS FOR THE ECOSYSTEM



A Foundation of innovation through national wide research platform

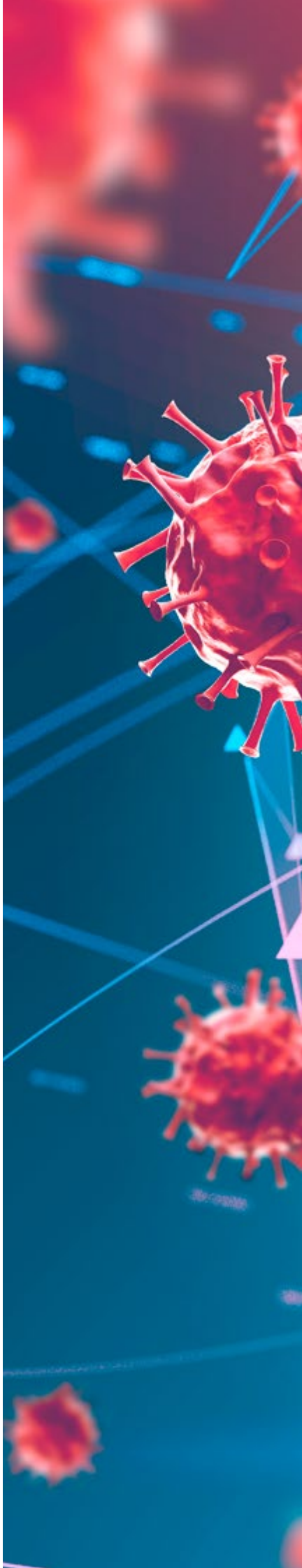
B Management of national scientific initiatives in response to epidemiological threats

C Culture of collaboration facilitating cross-organization links and management of public-private partnerships

D Bottom up progress monitoring to feed global planning scenarios and citizen communication

"Understanding how influenza viruses become human pandemic threats is vitally important to global health preparedness."

– Dr Francis S. COLLINS, NIH Director ,
Dr Anthony S. FAUCI, Director,
NIAID NIHNIH Statement
January 24th, 2013



CASE FOR CHANGE

DIRECT BENEFITS FOR ORGANIZATIONS

Dassault Systèmes Medidata's customers have achieved significant benefits in this area of the medical research innovation cycle.

The response to the crisis requires to be tailored to each country's specific dynamic. As new epicenters can appear almost daily, testing and tracing must be deployed rapidly and efficiently. Medical research is playing a cornerstone role in the global and regional strategies.

In the clinical trials ecosystem, we continue to see impacts on patient recruitment and retention as at-risk patients maintain quarantine while vaccines and therapies are in development.

The response to these challenges has been the increased use of and reliance on solutions like remote monitoring and trial virtualization. Interestingly and importantly, these may not be transitory solutions to an immediate problem; rather they may more and more become the standard.

We are committed to providing this data to our stakeholders, along with relevant updates from a regulatory perspective. And you can count on us to continually innovate to identify new solutions designed to help further clinical research.

Benefits include[1]:

Increased safety for study patients and site and sponsor personnel. Through innovative trial virtualization solutions, patients and study personnel can fully participate in the study from the comfort and safety of their homes and places of work. This mitigates challenges during the pandemic with patient recruitment, enrollment and retention for new and existing studies and reduces the risks and costs associated with travel of site monitors to investigative sites.

Increased efficiencies and effectiveness in trial conduct using a risk-based quality management approach. Virtual monitoring of sites (centralized and remote) results in faster study start up (2 weeks), 20%-40% reduction in edit checks by medical monitors, 83% reduction in case review time by medical monitors, ~50% automation of data reviews, and approximately 5 days (vs 4 weeks) from Last Patient, Last Visit (LPLV) to database lock (DBL) for critical studies bringing needed vaccines and treatments to market faster.

Enhanced quality through AI-assisted statistical analysis of data. Within 2 weeks, sponsors can review over 10 key risk indicators associated with data anomalies, quickly identifying potential issues with the quality of collected trial data at the site, country and study levels, mitigating the risk of regulatory non-approval.

While these are a snapshot of some of the benefits our customers see, we believe that the true value generated by deployment of our solutions is a multiple of that, which your research teams will realise as they adopt new ways of working, facilitated by the digital continuum. Additionally, integrating Dassault Systèmes solutions with existing systems creates an additional multiplier for overall efficiency, carrying momentum downstream.

> **"COVID-19 has demonstrated that sponsors and investigators can achieve in weeks what was previously thought to require months or years, and highlighted the humanitarian importance of efficient, robust and definitive clinical research. The industry's actions over the next 1–2 years may determine fundamental pivots for how medicines are developed, giving each stakeholder an opportunity not only to adapt but to shape the future clinical trial paradigm"[2].**

[1] Dassault Systèmes Estimate based on internal business expertise & analysis, as well as Voice of the customer: Customer Value Engagements (Assessment, Definition, Commitment and Delivery)

[2] https://www.nature.com/articles/d41573-020-00150-9

CASE FOR CHANGE

IMPACT TO CITIZENS

- Faster delivery of innovative vaccines, therapeutics and diagnostics
- Public updates on each step of key operations and scientific milestones
- Linking of scientific achievements to treatment and distribution models
- Connect patient care directly to basic research discoveries

While these are a snapshot of some of the benefits our customers see, we believe that the true value generated by deployment of our solutions is a multiple of that, which your research teams will realize as they adopt new ways of working, facilitated by the digital continuum. Additionally, integrating Dassault Systèmes technology with existing systems creates an additional multiplier for overall efficiency, carrying momentum downstream.

Opening the way to tests, drugs and vaccines.

"This infection is not going to disappear... without science leading us to vaccines."

— Jeremy Farrar, Director of UK Welcome Trust
(WEF Covid Action Platform, March 8th, 2020)

WHY DASSAULT SYSTÈMES

VALUE OF PARTNERING WITH DASSAULT SYSTÈMES

Dassault Systèmes offers a strategic partnership with unparalleled experience in transforming organisations in highly complex regulatory environments to assist with innovation transformation. Now more than ever, public health organizations and associated research institutions need a trusted, strategic partner that understands their vision and shares their passion for what is possible in today's rapidly changing global and technology-driven environment.

INTEGRATED LIFE SCIENCES & HEALTHCARE SOLUTIONS

Our innovative software solutions have being widely used by public and academic institutions (e.g. **Harvard, MIT, US FDA, NIH, UCSF, Imperial College London, Cambridge University, Cancer Research UK, Genopole, INSERM, Université de Strasbourg, FAU Erlangen Universität, Shanghai Jiao Tong University, Curtin University**) and private companies around the world specializing medical, pharmaceutical and healthcare industries.

DEDICATION TO SUSTAINABLE INNOVATION

Dassault Systèmes provides business & people with **3D**EXPERIENCE universes to imagine sustainable innovations capable of harmonizing product, nature and life. Dassault Systèmes was ranked #1 by Corporate Knights in their 2018 Top 100 Most Sustainable Company In The World. The ranking highlights our environmental, social, financial and innovation ability as well as the sustainability value of our company's solutions.

DELIVERING VALUE TO SCIENCE BASED ORGANIZATIONS

Dassault Systèmes is a proven partner that can help public research institutions discover life changing therapeutics that are more patient-centric within a complex scientific environment. Dassault Systèmes established partnership with multiple governmental institutions through the world, including US FDA, NIH and INSERM.

Dassault Systèmes, the **3D**EXPERIENCE 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 **3D**EXPERIENCE 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**.

DASSAULT SYSTÈMES COMPANY PURPOSE

"Dassault Systèmes provides business and people with **3D**EXPERIENCE universes to imagine **sustainable** innovations capable of harmonizing product, nature and life."

– Bernard Charlès, CEO Dassault Systèmes

NEXT STEPS

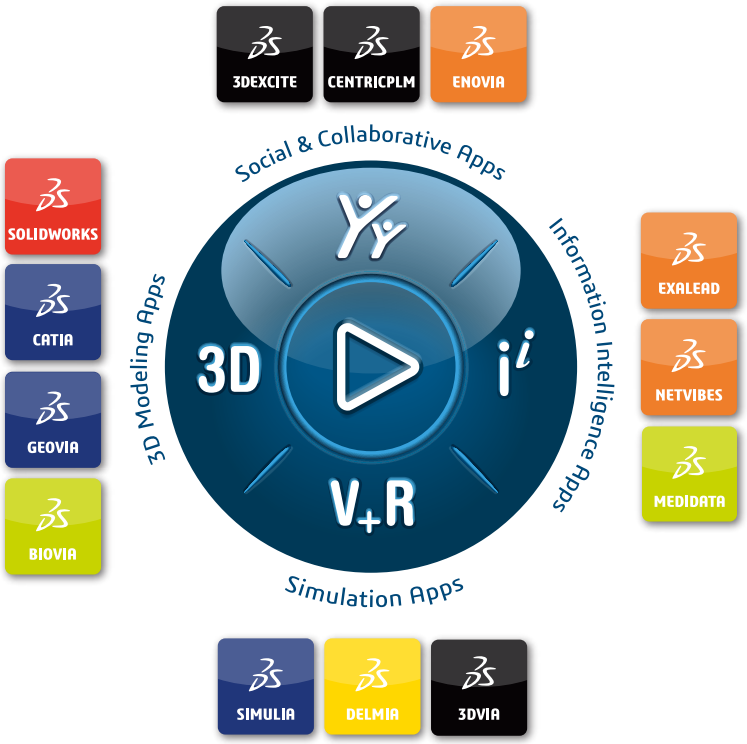
Our team is prepared to jointly engage with you to identify high value opportunities, develop a benefit case and build an implementation roadmap aligned with your priorities. We propose initial reviews with key stakeholders to explain the opportunities Dassault Systèmes can bring to their organizations. At the conclusion of our findings, we propose an executive workshop to define the approach, scope, and timelines necessary to codify the opportunity potential and develop a roadmap for implementation.

Recommended next steps for the transformation journey:

- Share and review Dassault Systèmes' Value Perspective with leaders and key stakeholders across the organization
- Plan a Value Assessment to build a mutual understanding of your specific strategy and challenges. Confirm and clarify any specific objectives and initiatives as well as any barrier towards this achievement
- Develop an agreed high level implementation roadmap aligned directly to high value opportunities, with established KPIs to measure success and a robust business case to justify any required investment

Achieving this bold vision for transforming the approach to game-changing therapeutics will require significant focus and leadership commitment along with a strategic business partnership with a company like Dassault Systèmes that is committed to enabling a successful outcome. Dassault Systèmes brings unparalleled experience and a strong track record that will help you drive innovation, quality and excellence to deliver sustainable solutions and improve public health.

Dassault Systèmes is committed to enabling a successful transformation program for you and your researchers. We look forward to growing the relationship and assisting you to achieve sustainable innovation strategy objectives.



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

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