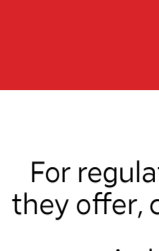




INFOGRAPHIC

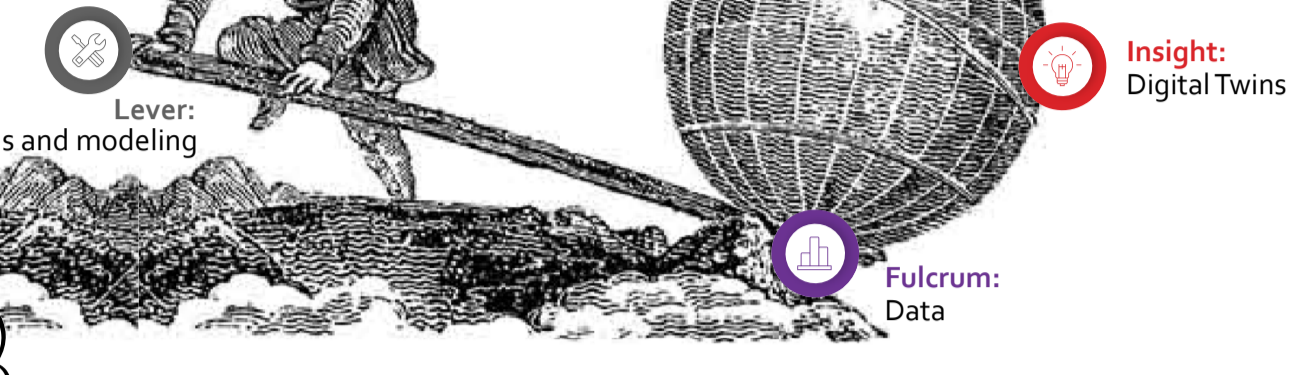
2022 CAPACITY AND MOBILIZATION ASSESSMENT

of the Pharmaceutical Industry Utilizing Digital Technologies to Optimize / Scale-Up Production



Can emerging technologies, such as integrated digital twin solutions, actually help manufacturers respond in an emergency scenario, such as a future pandemic?

This CARES Act funded project set out to evaluate this premise, and also implement such a technology, with a leading medical diagnostics manufacturer.



This CARES Act funded project gathered input from a wide set of industry stakeholders through surveys. It produced a Digital Twin Assessment framework for distribution to manufacturers more broadly. It also evaluated commercial off-the-shelf technologies and carried out a real-world technology implementation with a leading medical device manufacturer to demonstrate the value of an integrated digital twin solution (not just a software simulation) to help improve response speed and the quality of decision-making for emergency scenarios.

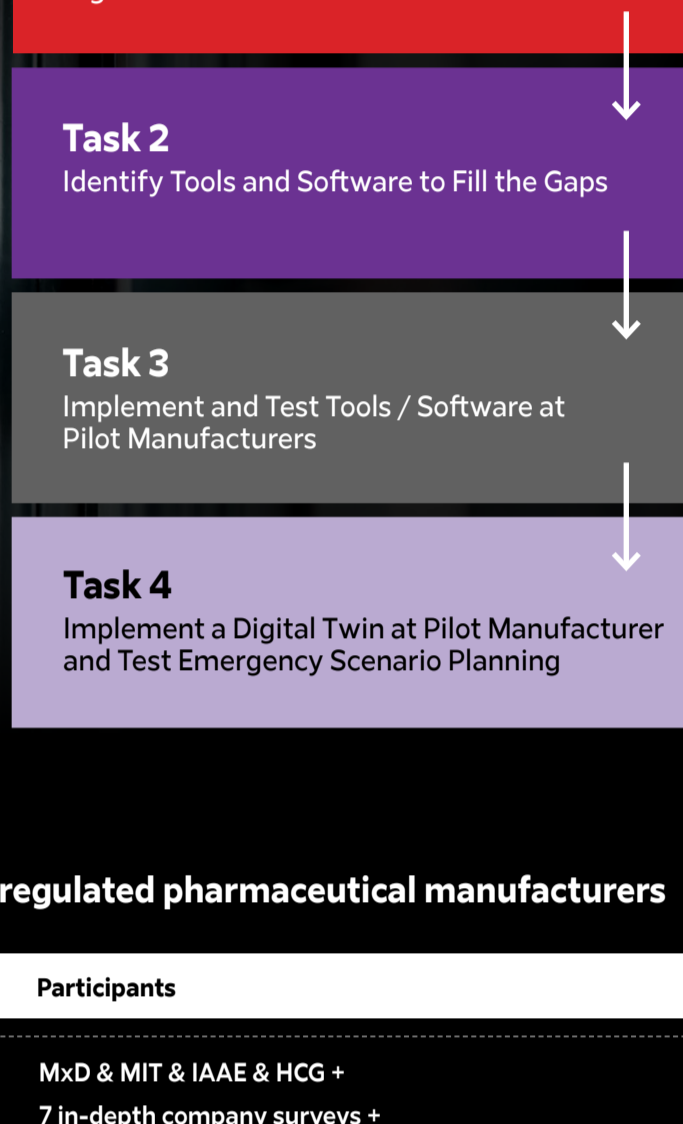
Labelled Archimedes diagram original credit to Pablo Rolandi, Director of Data Sciences at Amgen, Digital Twins of Processes, Products and Devices for Drug Development & Manufacturing Sep 2021

Digital twin insights can relate to performance predictions and process optimization, but can also enable insights into emergency scenarios, such as capacity predictions in times of product demand surge.

The research conducted under this project confirmed that the top three emergency scenarios faced by organizations during the COVID-19 disruption were:

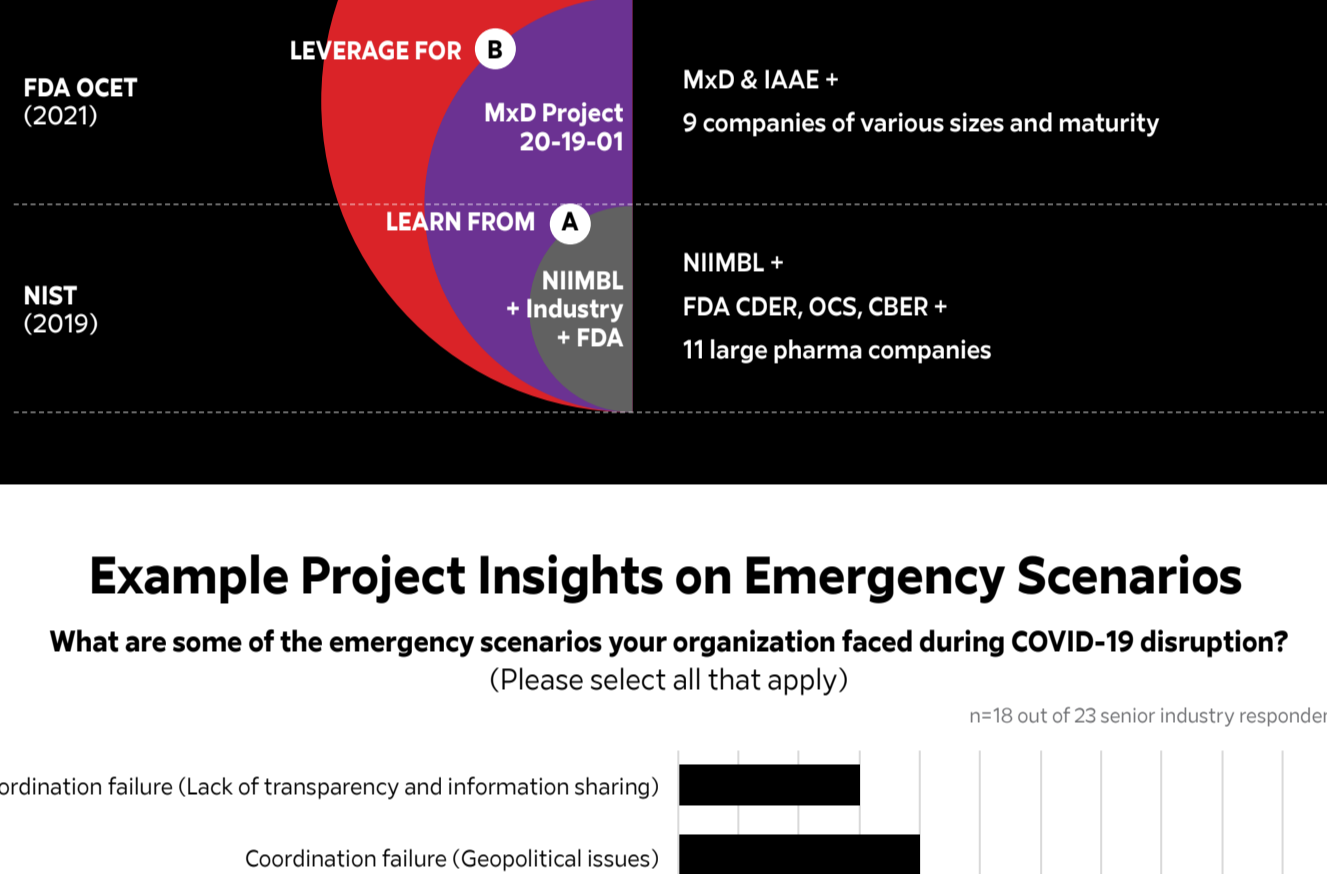
- 01 **Demand surge**
(Pandemics and other public health emergencies)
- 02 **Coordination failure**
(Disruption in transportation and delivery)
- 03 **Capacity reduction**
(Inability to ramp up production)

Project Design



Project context

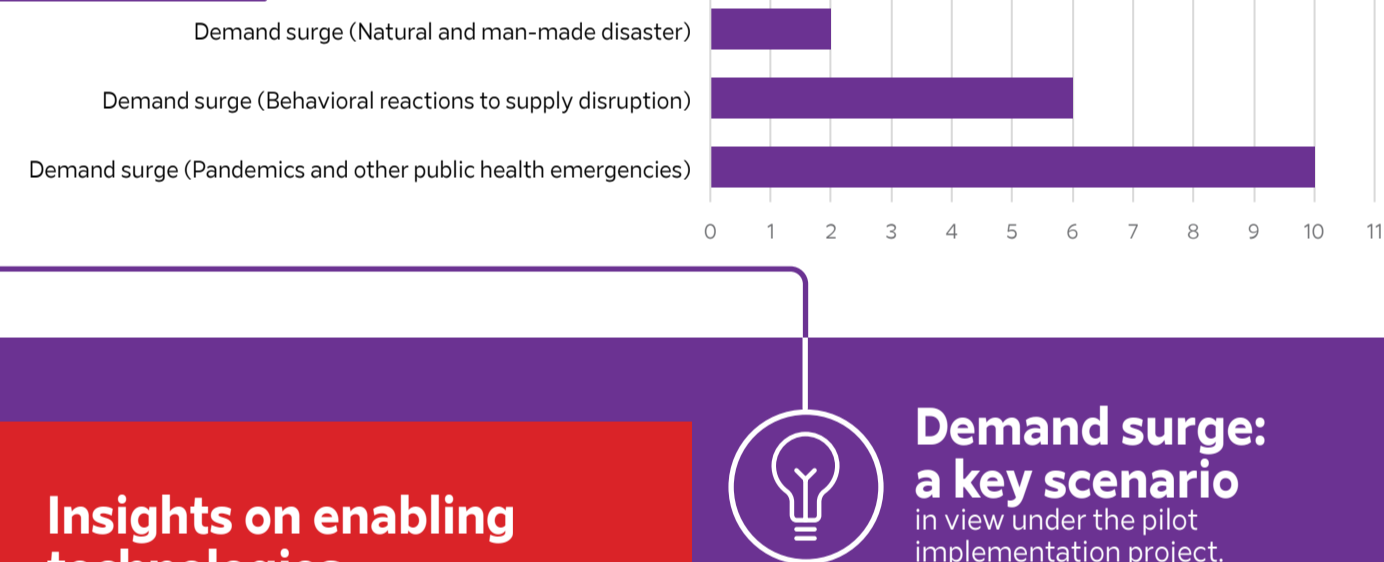
Illustrating the project connections for regulated pharmaceutical manufacturers



Example Project Insights on Emergency Scenarios

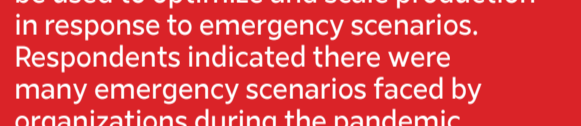
What are some of the emergency scenarios your organization faced during COVID-19 disruption? (Please select all that apply)

n=18 out of 23 senior industry respondents



Insights on enabling technologies

Manufacturers see digital twins as promising technology to optimize and scale production in response to emergency scenarios.



19 of 20

respondents in our second survey cited real-time digital twins and simulations, used to model entire systems, as an enabling technology they believe could be used to optimize and scale production in response to emergency scenarios. Respondents indicated there were many emergency scenarios faced by organizations during the pandemic.

Demand surge: a key scenario

in your under the pilot implementation project.

Surprisingly, only 35% of respondents are aware of any digital twin maturity or assessment frameworks that their organization uses or could benefit from.



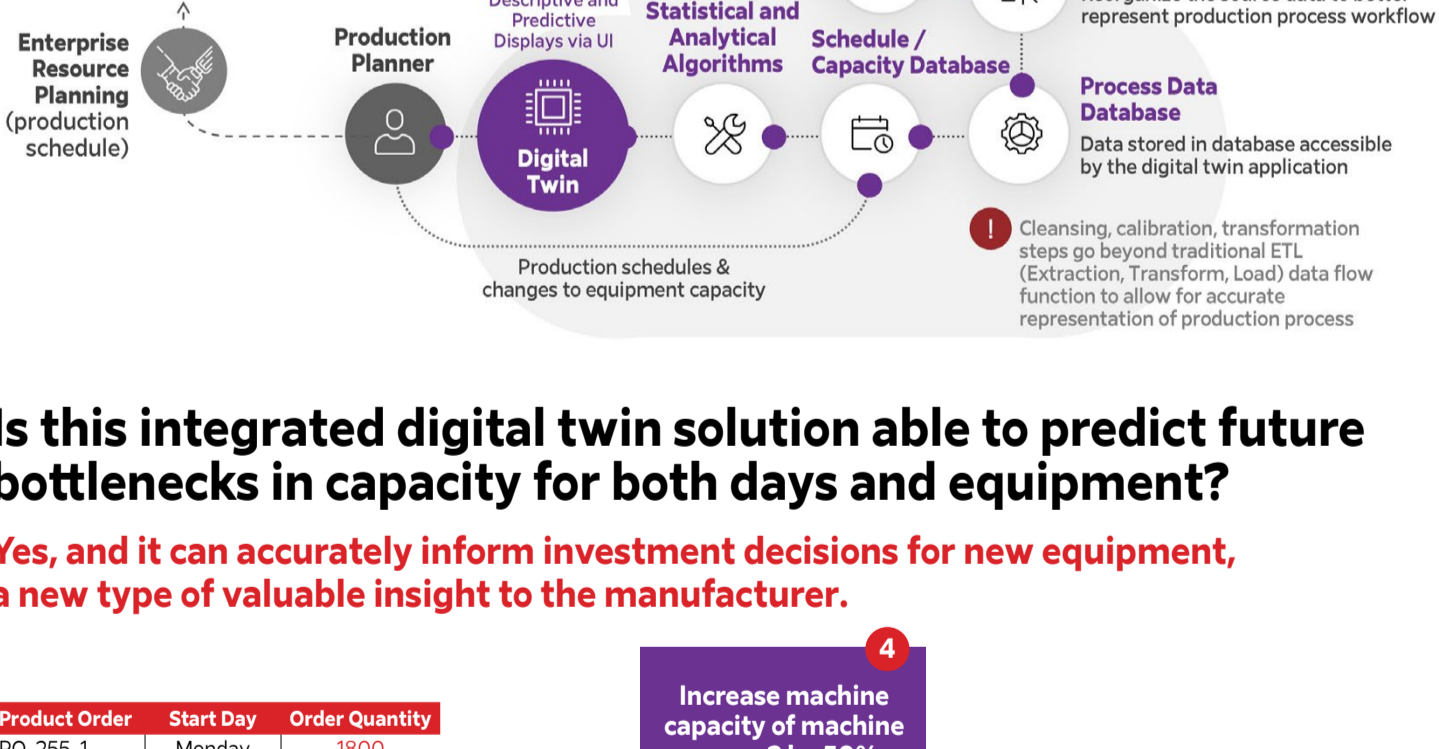
What does our research suggest may have changed since 2021?

Optimism about digital transformation appears to be significantly increasing.



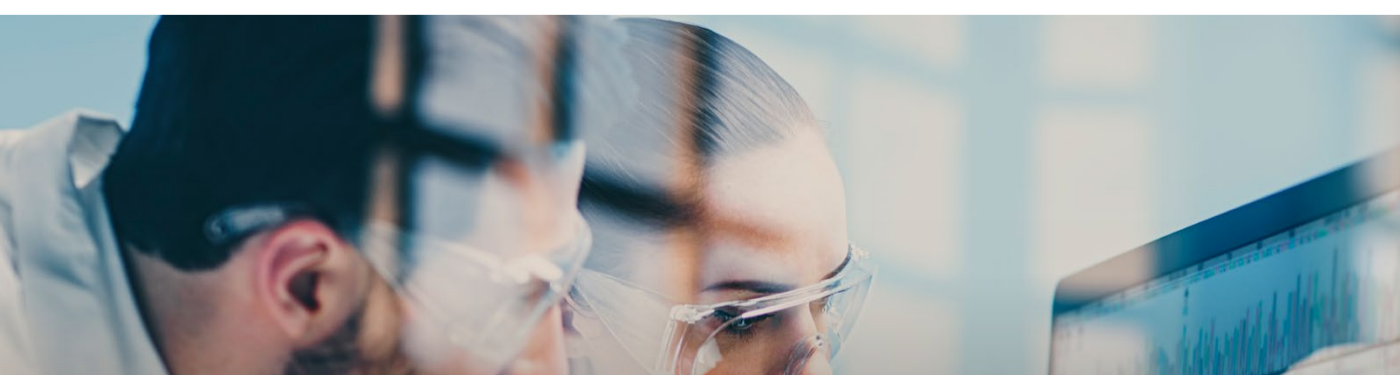
of survey respondents in our second survey say they are **optimistic or very optimistic** about digital transformation in their organization during the next twelve months. In a prior 2021 FDA OCET funded study, less than half were optimistic while the others were neutral.

For this pilot manufacturer project notice the data flow from the physical twin through the integrated digital twin solution and back to the physical twin via the production planner and ERP system.



Is this integrated digital twin solution able to predict future bottlenecks in capacity for both days and equipment?

Yes, and it can accurately inform investment decisions for new equipment, a new type of valuable insight to the manufacturer.



66 The integrated digital twin makes specific bottleneck predictions relating to products.

Predicted daily machine hours more than available machine capacity by machine groups (%)

Machine	Mon	Tues	Wed	Thurs	Fri
MC_G1					
MC_G2					
MC_G3	40%	40%	44%	44%	37%
MC_G4					
MC_G5					

Key recommendations to manufacturers and practitioners

- 01 **Advanced technologies require businesses to develop strategic software capabilities, even for manufacturers whose core competencies lie in hardware.**
- 02 **Data readiness will also need data readiness and data management maturity to make the most of digital twins.**
- 03 **Although manufacturers need both technical and data readiness to successfully implement a digital twin, the decision to implement a digital twin should be made for business reasons rather than technical ones.**

“If we had to, all of a sudden, build 50% more than we are right now, I can plug that into the tool and I would be able to see specifically where we would have issues... It does have quite an impact because we know where the bottleneck is. I would be using the digital twin to do a lot of scenario planning.”

- A senior production planner at the pilot manufacturer

Access the full set of conclusions and recommendations in the project report or view the Executive Summary slides.

To stay informed about the release of this and other projects and research see below:

- > follow MxD
- > follow IAAE
- > follow HCG
- > follow MIT