PharmaSUG 2021 - Paper SA-211

How simulation will impact the future of Healthcare & Life Sciences

Pritesh Desai, Allison Sealy, Shawn Tedman, Lois Wright and Bahar Biller, SAS Institute Inc.

ABSTRACT

Simulation is a way to model a real-life or hypothetical process so that it can be studied to understand how the system works. By changing the parameters in simulation, predictions may be made about the behavior of the system. Current simulation models in Healthcare and Life Sciences lack the details needed to glean valuable insights. This paper will review the current state of simulation in the Healthcare and Life Sciences space and provide relevant examples of recent projects completed in partnership with the SAS Operations Research Center of Excellence. A roadmap of future trends, developments, and discussion of how machine learning will play a role and improve patient outcomes.

INTRODUCTION

Gaining visibility into healthcare and life science system operations and managing the risks to which these complex systems are exposed are two of the key challenges faced by many companies. At SAS, we recognize the importance of overcoming these challenges and equip our customers with the power to predict and optimize the future performance of their systems via the use of advanced analytics. Whether a decision concerns forecasting, capacity planning, or supply chain management — first understanding, then modeling, and finally mitigating risk is crucial to the competitiveness of any firm.

At the heart of advanced analytics solutions at SAS, there is a flexible, data-driven, and scalable system simulation that helps address the needs of our customers in the healthcare and life science domain. In today's uncertain world, the capability of creating a digital copy of the actual system is one of the most powerful analytics tools available especially when making decisions under uncertainty. A digital copy can also be created for a system that has not been built yet to aid in its design as well as to support strategic investment decisioning. The main features of stochastic and dynamic system simulations at SAS are as follows:

- Mimics the flow of various objects through a complex process constrained by resources.
- Provides enhanced visibility into the future of system operations.
- Enables the analysis of thousands of scenarios to perform risk-and-return tradeoff and presents opportunities to establish resilient systems for healthcare and life sciences with minimum total cost.

Examples of complex systems, for which SAS utilizes this advanced capability, range from clinical trials and the drug discovery process to hospitals and global healthcare supply chains. SAS has been helping its customers from a variety of industries ranging from healthcare and life sciences to consumer-packaged goods, aerospace, and defense. Particularly for the work done in the healthcare domain, SAS was recognized as a recipient of the 2017 North Carolina Technology Association's Beacon Award for the best use of technology in analytics. Through further integration, SAS' advanced analytics software enables representation, simulation, and robust optimization of large-scale and dynamic healthcare systems and their operations. The resulting integrated digital solution plays the role of a digital twin (a digital copy of the system being designed) of the actual process. This scalable and data-driven digital twin can be used for several purposes:

- To predict various performance indicators and to gain visibility into the future of system operations.
- To assess the impact of operational policy and strategic investment decisions prior to decisioning.
- To stress test any healthcare and life science system and identify best courses of action to take if faced with disruptive events.

Because of the additional information acquired from the digital twin, our customers are able to make more informed decisions to enhance resiliency with reduced cost and increased quality of service. The key to the

success of achieving these objectives is to empower our customers with the SAS technology at a time when improving healthcare system resiliency and risk mitigation is more critical than ever.

Any digital twin of a system plays the role of a virtual laboratory that replaces the need to build out a real-world system or a physical model for collecting data about the best course of action to take. Thus, it incurs less cost and carries less risk. Furthermore, it enables the study of many alternate system configurations as well as the creation of many alternate scenarios for each configuration. A high-level illustration of the value that can be gained from such a solution is presented in Figure 1:

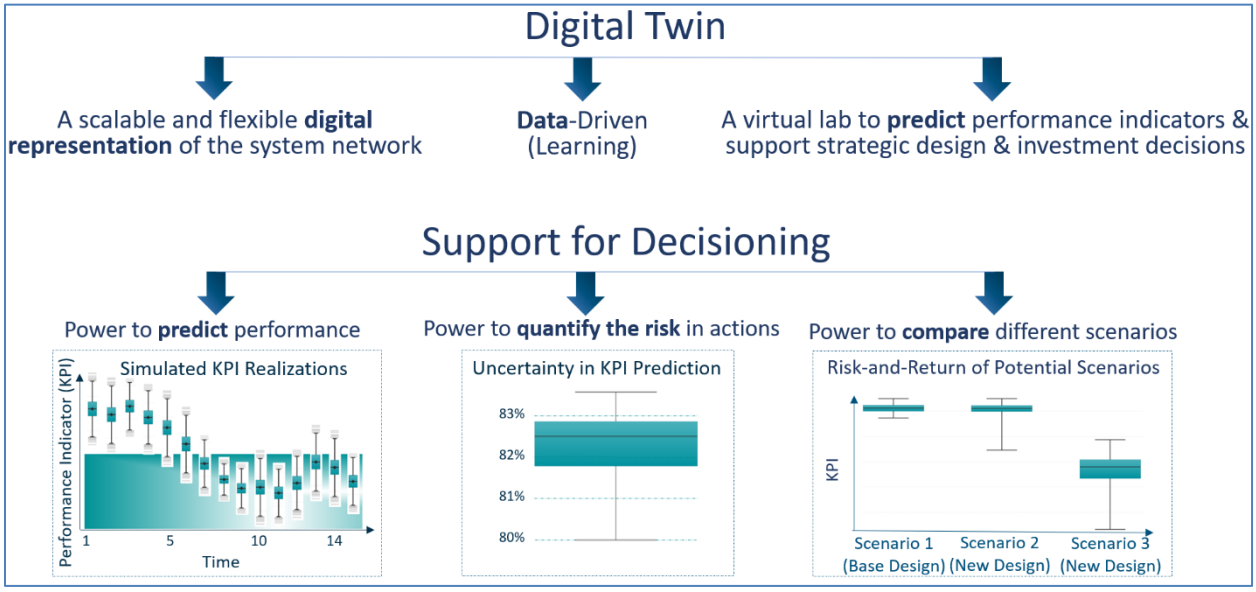

Figure 1. Benefits of a Digital Twin Framework

Consequently, the digital twin allows the users to amass large amounts of data very quickly. This large dataset contains all the information about the dynamics of the system, interactions, and interdependencies among all system components (as well as the details on the propagation of the uncertainty throughout the system) coupled with all business rules and resource constraints in place. This dataset also contains the evolution of time. Therefore, the simulation output data — which may be referenced as the sample-path data — contains voluminous information and vital insights that are often hard to surface. This is when machine learning arises as an invaluable tool to understand the simulation-generated data. The sizable data presents a unique opportunity to gain detailed insights into system performance and response to changes in an accelerated and automated manner. It is for this reason that simulation and machine learning naturally align to develop integrated solutions with the additional benefit of real-time enablement.

Our view of any system simulation is that it is a big data generation program, reflecting what may happen in the future in response to changes to the existing system operations in place. Machine learning accelerates the prediction of key performance indicators (KPIs). Integration with machine learning allows the results from scenario analyses to be presented near real-time. However, this is not the only example of how simulation and machine learning may provide value. Machine learning can be further utilized to generate data to drive the simulation both prior to and during the simulation process. Additionally, simulation can be used to mimic an environment and help train artificial intelligence to contribute to the advances in healthcare and life science.

In the following sections, we will introduce the process of simulation development and then describe a use case built on the acceleration of simulation with machine learning. We will then review an enhanced use of simulation, machine learning, and artificial intelligence to deliver real-time enablement and conclude with a roadmap of future trends.

SIMULATION DEVELOPMENT FOR HEALTHCARE AND LIFE SCIENCE SYSTEMS

Simulation is an operations research technique which enables users to build models of large-scale, stochastic, and dynamic business systems. The first step of simulation development is to obtain a detailed description of the business process flow. An example of a process flow could represent patient enrollment in a clinical trial. Another process flow example could be the stochastic arrival and resource-constrained flow of patients through the pods of an emergency department. A third process flow example could be a healthcare supply chain process - the flow of supplies and medical equipment through a network of channels to meet the demands at various clinics and hospitals. Each of these example systems has the following three characteristics which would make it a candidate for a digital simulation study:

- A complex resource-constrained process flow.
- High input variability (i.e., high exposure to risk).
- Key performance indicators that are difficult to predict with high accuracy.

It is important to emphasize the key challenge of managing resource constrained processes — which are the type of processes for which the use of simulation for modeling and analysis would provide the largest value. In the clinical trial enrollment process flow, resource constraints can be the sites at which the study is performed, as well as the personnel needed to activate each site for enrollment eligibility. In an emergency department, lack of availability for beds, nurses, and doctors may be the main resources constraining the patient flow. Finally, in a supply chain, unreliable suppliers, manufacturing plant shutdowns, and transportation network bottlenecks are all examples of resource constraints challenging successful supply chain management. The objective of the model building effort for such complex resource-constrained systems is to create a digital representation of the process flow currently in place and use the resulting model as a virtual laboratory to predict the KPIs. The following list provides examples of KPIs:

- For clinical trial enrollment process flow, the number of patients enrolled in the study and the total cost incurred to carry out the entire study.
- For an emergency department, length-of-stay from time of admission to time of discharge.
- For supply chain, the frequency of on-time fulfillment.

After being equipped with the KPI prediction capability, simulation can be used to understand how the system would perform under various conditions with the purpose of collecting insights about the best course of action to take in the future. Conducting a digital simulation study would, however, come with its own set of challenges:

- The simulator should allow flexible as-is modeling.
- The simulator is scaled appropriately and driven by data and information.
- The simulator’s building blocks should allow automated output data collection.

SAS’ simulation technology overcomes each of these challenges and is at the heart of scalable, data-driven, and flexible digital twins that have been developed for various industries.

Another aspect of the first step of simulation development is to collect all relevant information and data which would fully describe the system of interest. Combining the system process flow with all necessary pieces of information and data completes the descriptive analytics component of the solution development.

The next step of simulation development is to characterize the uncertainty associated with each stochastic input variable of the system. An example of a stochastic input variable is the arrival process that initiates the business flow in place. Furthermore, the arrival process could be non-stationary, i.e., the expected number of arrivals may change from month to month, as well as from week to week, and even from day to day. In addition to the arrival process, there may be hundreds of other stochastic input variables to be considered. Naturally, each of the inputs contains an uncertainty characterization and the propagation of the input uncertainty through complex process flows can be a daunting task. Simulation is the solution for this complicated task that may appear impossible at first glance.

Input uncertainty characterization is followed by design of the simulation experiments where the levers that

could be changing during a scenario analysis are defined. It is the definition of those levers that enable what-if analysis and robust system optimization. In a clinical trial simulation for example, the levers may be country startups and site activations. In an emergency room simulation, the levers could capture the bed availability and staffing decisions. Finally, in a healthcare supply chain, the levers may represent inventory control and fleet management policies in place.

The design of the experiments are followed by the execution of the simulation, which generate vast amounts of data representative of how the system under consideration may perform in the future. By taking advantage of statistical analysis and visual analytics toolkits, the risk profiles for system KPIs are obtained, completing the predictive analytics component of the solution development. The scenario analysis can be further accelerated via the use of machine learning techniques and we describe such acceleration for a use case involving clinical trial enrollment in the following section.

The prescriptive analytics component of the solution development involves integration of the descriptive and predictive analytics described thus far with optimization for the purpose of identifying the best course of action to take when faced with unplanned events to achieve resiliency. Figure 2 presents a high-level illustration of a framework integrating descriptive, predictive, and prescriptive analytics and represents an environment that incorporates learning and improving, while optimizing the system operations with the goal of producing a resilient system.

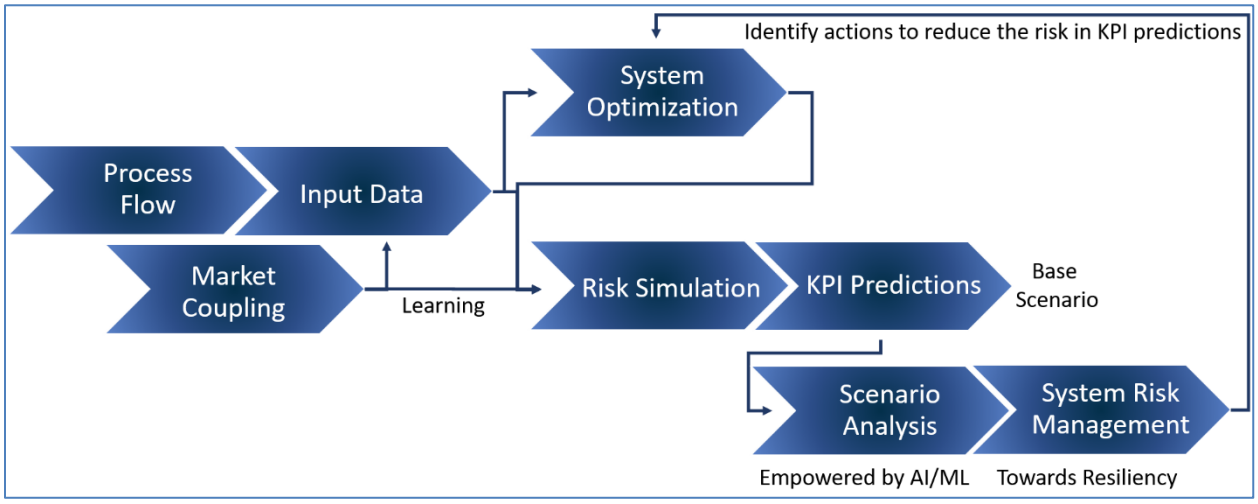

Figure 2. An Integrated View of Descriptive, Predictive and Prescriptive Analytics

INTEGRATED USE OF SIMULATION AND MACHINE LEARNING

The motivation behind the integration of simulation and machine learning is three-fold: (1) data availability; (2) computation capability; and (3) real-time decisioning needs of our customers. As illustrated in Figure 1, simulation is often developed to serve the purpose of a virtual laboratory and equipped with the capability to generate many sample paths to help users predict the future. Despite the availability of enormous computational capability, conducting simulation experiments and performing the statistical analytics to provide the resulting predictions take time. However, scenario-based risk analysis resulting from such direct use of simulation may fall short of meeting the customers' real-time decisioning needs. One approach to mitigate this shortfall is to use the large datasets generated from the virtual laboratory setting for training and testing machine learning and deep learning models to replace simulation for Real-Time Prediction and Real-Time Control and Optimization. These two objectives — which are illustrated in Figure 3 — have been successfully achieved at SAS, within the context of clinical trial enrollment planning, and the resulting work was presented at SAS Global Forum in 2019. Figure 3 shows how machine learning can be utilized during the post-processing step of a simulation study. However, machine learning and deep learning trained sub-models can also be combined in a system simulation. This leads to the simulation of system-of-systems, building on the same framework illustrated in Figure 2. The following section further explores the use cases for clinical trial enrollment planning and capacity management in medical facilities.

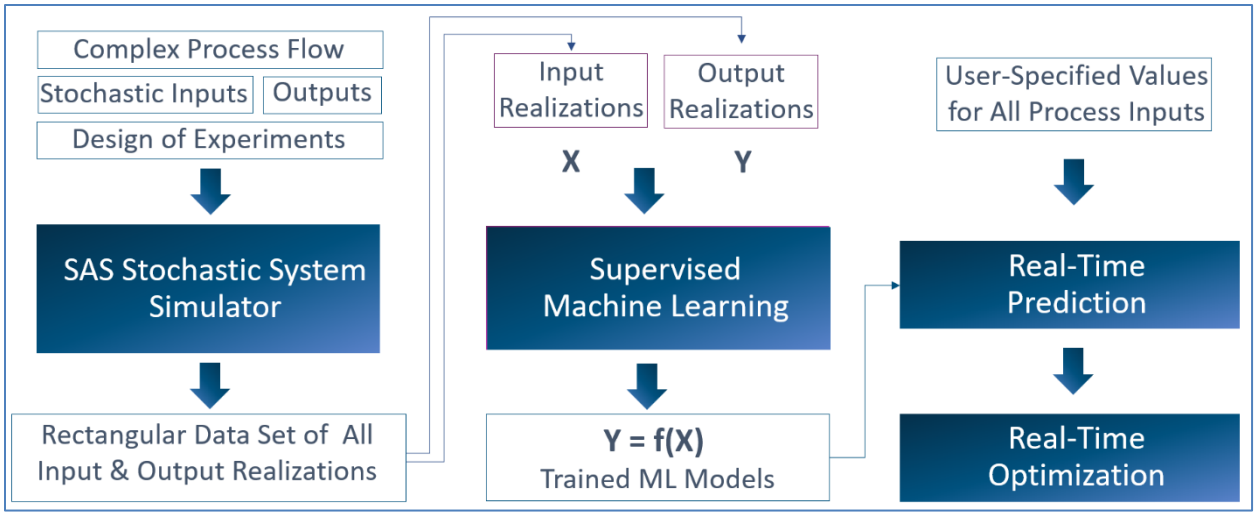

Figure 3. Prediction and Prescription of KPIs in Real Time

CASE STUDIES

First, we present a use case for clinical trial enrollment planning and demonstrate how SAS combines simulation and machine learning to provide real-time predictions for clinical trial research organizations and pharmaceutical companies. The second use case addresses the need for capacity management at medical facilities. The subsequent section explores industry trends in the healthcare and life sciences domain.

CASE STUDY 1: ACCELERATED PREDICTION VIA SIMULATION & MACHINE LEARNING

In this section, the focus is on the problem of clinical trial enrollment planning. Enrollment plans are designed for every clinical trial by pharmaceutical companies and clinical research organizations. The objective is to enroll a target number of patients as quickly and cost effectively as possible; thus, the key performance indicator is the number of patients enrolled in the clinical trial within a pre-specified amount of time, such as a number of months.

The characteristics and challenges of clinical trial enrollment planning can be overcome by selecting simulation and machine learning as the technologies of choice. The first four characteristics, listed below, are enabled by the simulation. The simulation further utilizes the experimental design to help identify the course of action to take in response to changes in the system and/or its environment. A high-level description of a clinical trial enrollment simulation and details of its design are shown in Figure 4. The last challenge is, however, overcome by the integrated use of simulation & machine learning:

1. A complex patient enrollment process.
2. High input variability in startup delay, enrollment capacity, enrollment rate, screen failure probability.
3. High variability in the number of patients that can be enrolled in the clinical trial over time.
4. A solution which is data-driven and scalable with the number of countries and sites under consideration.
5. A solution that enables patient enrollment prediction, in real-time, in response to the following sample questions:
    - What would patient enrollment be 13.5 months after the trial starts. where the site enrollment capacity is 200 patients, and the patient screen failure probability is 20%? Each of these points being different from the assumptions of experiments that have already been conducted by simulation.

- What would enrollment prediction be six months later under the identical assumption changes listed in the previous point?
- What if site enrollment capacity was reduced by 10%?
- What if site enrollment capacity were reduced by 40%?

The reason for utilizing a tool beyond simulation to answer the set of sample questions posed in point five above is two-fold: (1) the designed enrollment plan may not have been simulated for the settings described and (2) the sponsors of clinical research organizations and pharmaceutical companies need answers to their specific questions — examples of which are listed above — in real-time. Despite all the benefits of a simulation study, it is not possible for simulation to directly respond in real-time. It is possible, however, for simulation to enable clinical research organizations and pharmaceutical companies to answer the questions in real time.

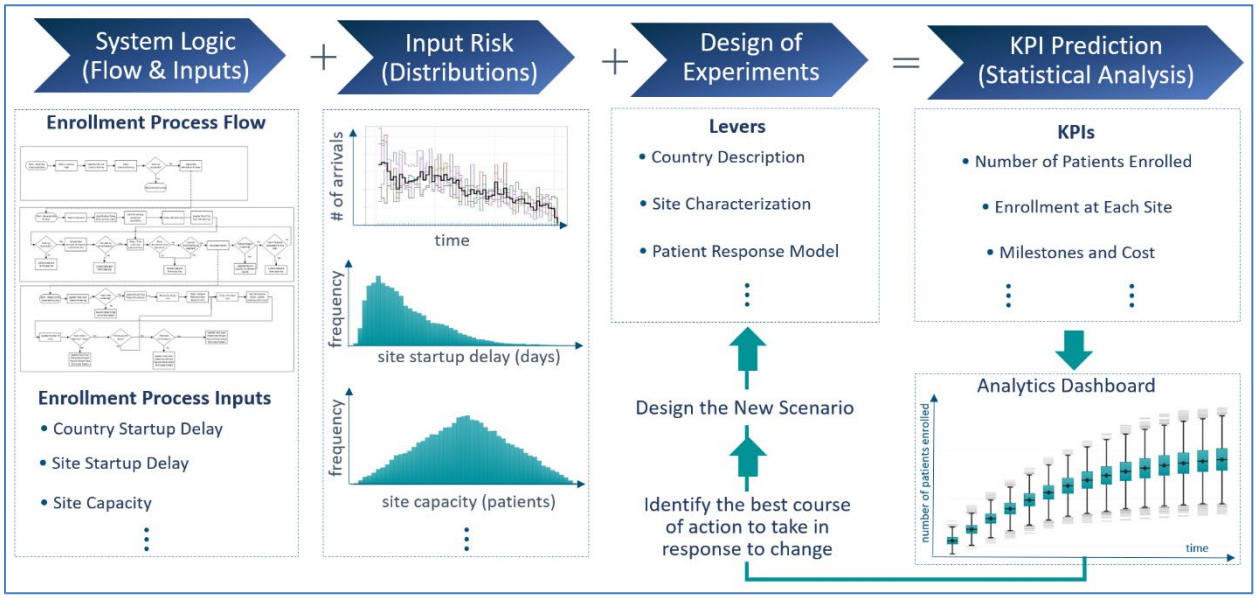

Figure 4. A High-Level View of a Clinical Trial Enrollment Simulation

Simulation of an enrollment process is a big data generation program. Simulation can be designed to generate output data representative of thousands of scenarios. The resulting data set can then be analyzed by supervised learning algorithms and an accurate meta-model of the dynamic system can be identified. It is this meta-model — which can also be referred to as the surrogate model — which would be used to answer the sponsors' questions in real-time. Biller et al. (2019) provides both the accuracy measured by root mean squared error and the prediction run time for an example clinical trial study and demonstrates the success of such integrated use of simulation and machine learning when used together with simulation for the purpose of accelerating scenario analysis and answering various what-if questions.

The benefit of the resulting surrogate model is not restricted to the enablement of real-time prediction. It also enables the prescription of actions in real time because the optimization technology at SAS successfully solves optimization problems whose constraints and/or objective functions are represented by surrogate models despite the lack of any closed-form representations for the underlying machine learning models. In particular, the problem of site selection — as part of clinical trial enrollment planning — falls into this category. An example problem would ask, for the selections of the sites to activate, which of these selections would minimize the time it takes the 0.95-quantile of the enrollment to exceed a target number of patients, say 800 patients (Biller et al. 2019). The solution would lead to the delivery of an efficient frontier of target KPI values and minimum timelines; see Figure 5 for an example illustration. Implementation details on the integrated use of optimization and machine learning models at SAS can be found at a recent SAS blog (Summerville, 2021).

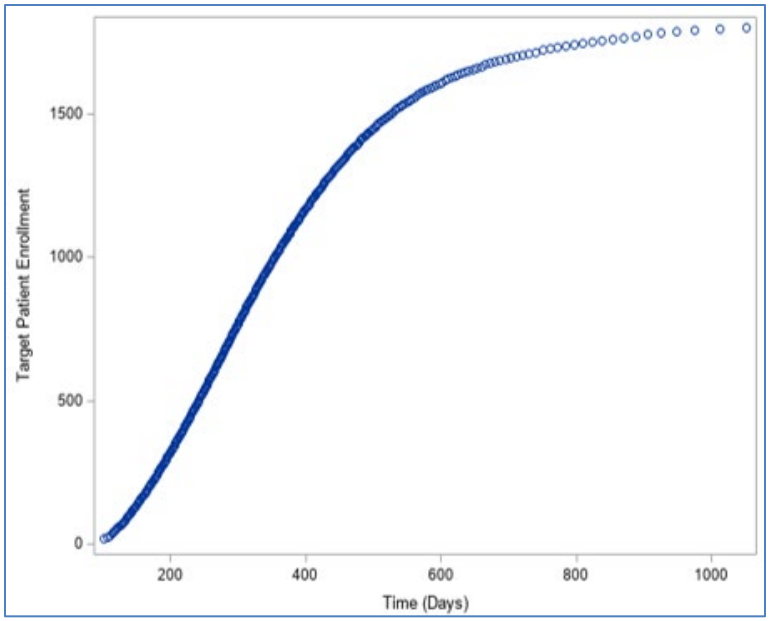

Figure 5. An Efficient Frontier for Site Selection: Target Enrollment (Y-axis) and Minimum Number of Days until the Achievement of the Target Enrollment with at Least 95% Probability (X-axis)

CASE STUDY 2: MEDICAL FACILITY MANAGEMENT VIA PATIENT FLOW SIMULATION

Capacity management at medical facilities is an area for which hospital patient flow modeling and simulation are of great value. The objective of the case study of interest in this section is to predict medical facility and patient flow key performance indicators. The use of a framework illustrated in Figure 4 for medical facility operations and the flow of patients is utilized to perform a comprehensive scenario analysis. Through integration with machine learning, hospital staff are equipped with the power to instantaneously observe the impact of changing levers to control outcomes and to identify the scenarios in which it would be possible to reduce the number of unserved patients while also reducing the average patient flow time.

More specifically, consider the 2017 case study of the Neonatal Intensive Care (NICU) Simulation project conducted by SAS in collaboration with Duke University. SAS created a stochastic simulation model for the NICU's patient mix and attained the following objectives:

- More accurate nurse scheduling.
- Better match between nursing ratios and acuity.
- Better preparation for future changes based on modifications of physical structure, staffing, referral patterns, and patient mix.
- Optimized balance between cost and quality.

An outcome of this project was that SAS was the recipient of North Carolina Technology Association Beacon Award for the Best Use of Technology in Analytics. As per Nurcan Bicakci Arcan (SAS Press Release, 2016), stochastic simulation modeling with advanced analytics gives organizations a fast, effective, and non-intrusive means to perform what-if experiments without disrupting their real-world systems. Workflow-oriented industries like manufacturing, retail, and finance have used discrete event modeling for decades to gauge how different scenarios might affect business operations. Now, a growing number of health systems are adopting the technology, which DeRienzo calls "the Rosetta stone" for performance and quality improvement in health care settings.

"I think health care in 10 years will necessarily look very different from health care now, and we are right in the middle of that transition," said DeRienzo. "This project is just one example of how we can use innovative analytics tools to improve not only the ways we provide care but the actual care we provide. Analytics has a tremendous role to play in facilitating that transformation – not just in the NICU but across the clinical spectrum."

It is often the case that tools similar to Duke's NICU simulation initially require data scientists to run the models. However, it is of critical importance to accompany the development with an easy-to-use and insightful user interface, which would make the tool independently accessible to everyday users like medical directors, nurse managers, and hospital administrators. Using advanced analytics techniques in an integrated manner will continue to provide value for hospitals and emergency departments that are under high pressure for managing their limited resources ranging from beds and equipment to nurses and doctors.

INDUSTRY TRENDS

The current healthcare and life science teams of researchers, scientists, and engineers who are looking into simulation and optimization solutions want an easy to interpret user interface (UI), available in their hands via an application or a web browser, that utilizes cloud computing because speed and performance are vital to their work. In the two above case studies, simulation runs are hidden from researchers and scientists. With a browser-based UI, parameters are easy to enter. With a few clicks of a button, the results of a simulation run are delivered into the hands of researchers and scientists working on a simulation problem. A 2018 PharmaSUG paper as well as a 2017 SAS Press release, show detailed examples of how this is achieved.

Per the U.S. Food & Drug Administration (FDA), artificial intelligence (AI) and machine learning (ML) based technologies have the potential to transform healthcare by deriving new and important insights from the vast amount of generated data during the delivery of healthcare every day. The ability for AI/ML to learn from the real-world and improve its performance makes these technologies uniquely situated among software as a medical device (SaMD).

The vast amount of data needed by SaMD based architecture, is not readily available. As a result, the role of simulation will increase as the vast amount of data needed to test the system can be easily created by a few parameters as explained in the integrated use of simulation and machine learning section. The future trend is leaning towards simulation-based systems for data generation, to mimic real-world scenarios, scenario analysis, stress testing of the system, risk identification, and risk appetite management.

Per the 2011 PharmaSUG paper on Modeling and Simulation in Drug Development, Munsaka and Carniello, have identified and assessed how SAS software is being used as a tool in clinical trial modeling and simulation within drug development. The authors of the book titled *Modern Approaches to Clinical Using SAS: Classical, Adaptive, and Bayesian Methods*, talk about current and future approaches to clinical trials. Finally, the paper by Hummel, Wang, and Kirkpatrick further review the future of clinical trial simulation, in the context of the great value that a simulation-guided, adaptive design, has to offer to optimize trial designs and decisions based on simulations. As per the case studies described above, SAS software can help customers envision the end-to-end simulation guided platform to mimic real-world systems to target their desired and unique set of KPIs.

As quality of software architecture improves, the future trend in simulation is leaning towards *appification*. According to Forbes, as apps become easier to build and with the advent of low code or no code technology, it is becoming more economical and relevant for researchers and scientists in simulation communities to be part of the appification process. With improved machine intelligence in appification, demand and adoption will increase with a shift towards mobile and touch-based devices.

For SAS, the appification process is not new. Applications created by SAS and Cleveland Clinic are free for public use and feature real-time COVID-19 pandemic data aimed at boosting preparedness and mitigation efforts. A Boemska (now owned by SAS) powered SAS Viya App, implements an alternative interface to the same resource optimization and forecasting code that powers the SAS Visual Analytics-based Cleveland Clinic application. Per Boemska, it focuses on simplicity, minimal load time, and context switching efficiency. See Figure 6 to Figure 9 below for examples.

Per Boemska, usability within a clinical setting is a primary consideration. The app is designed to be usable while wearing gloves and other personal protective equipment (PPE), and runs on easy-to-sterilize devices (i.e., tablets). While the design primarily targets the iPad® and Apple Pencil®, the app will work just as well

on similar Android™ OS, Windows® OS or Chrome OS™ stylus-enabled mobile devices. Figures 6 through 9 shown below are running on a 10.5” 2017 iPad Pro®.

SAS has a long history of working with healthcare and life science organizations and is active in the response to COVID-19 in these industries and others. The models developed in collaboration with the Cleveland Clinic apply advanced analytics to data to help hospitals optimize the use of medical resources like ventilators and hospital beds.

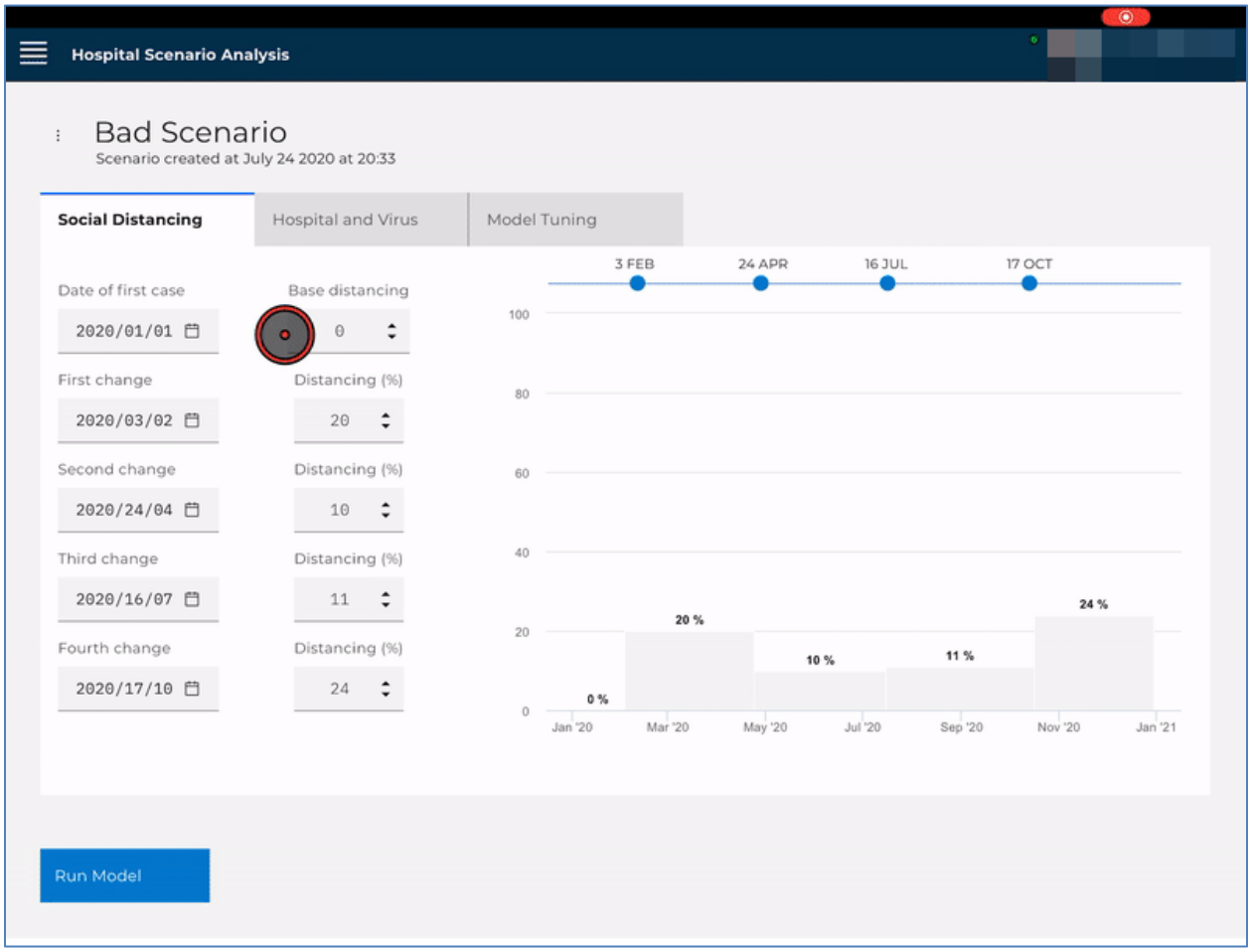

Figure 6. The resulting models include flexible control of model parameters and different model approaches that consider regional health and demographic variations and state-level assumptions.

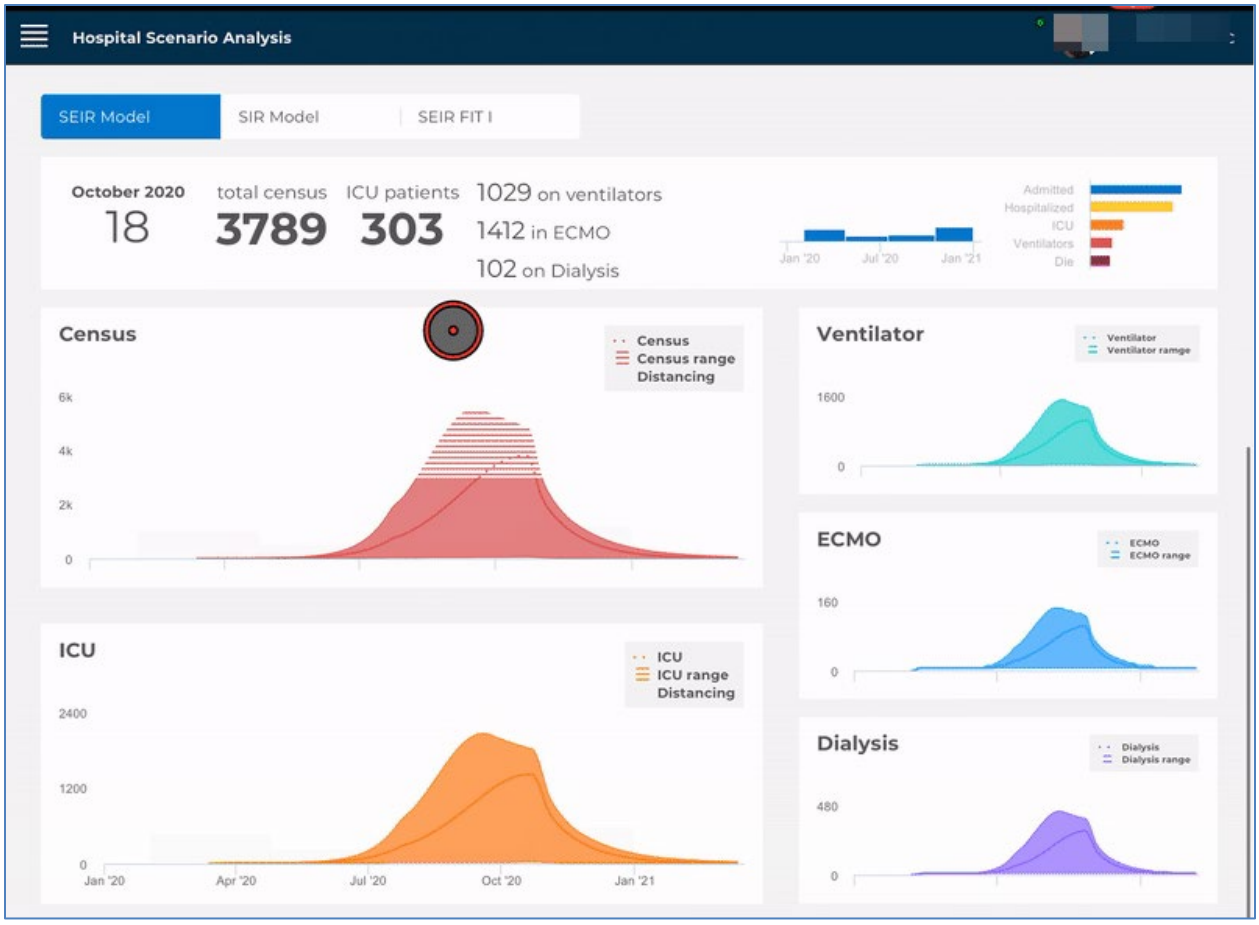

Figure 7. SEIR (Susceptible-Exposed-Infected-Recovered) MODEL

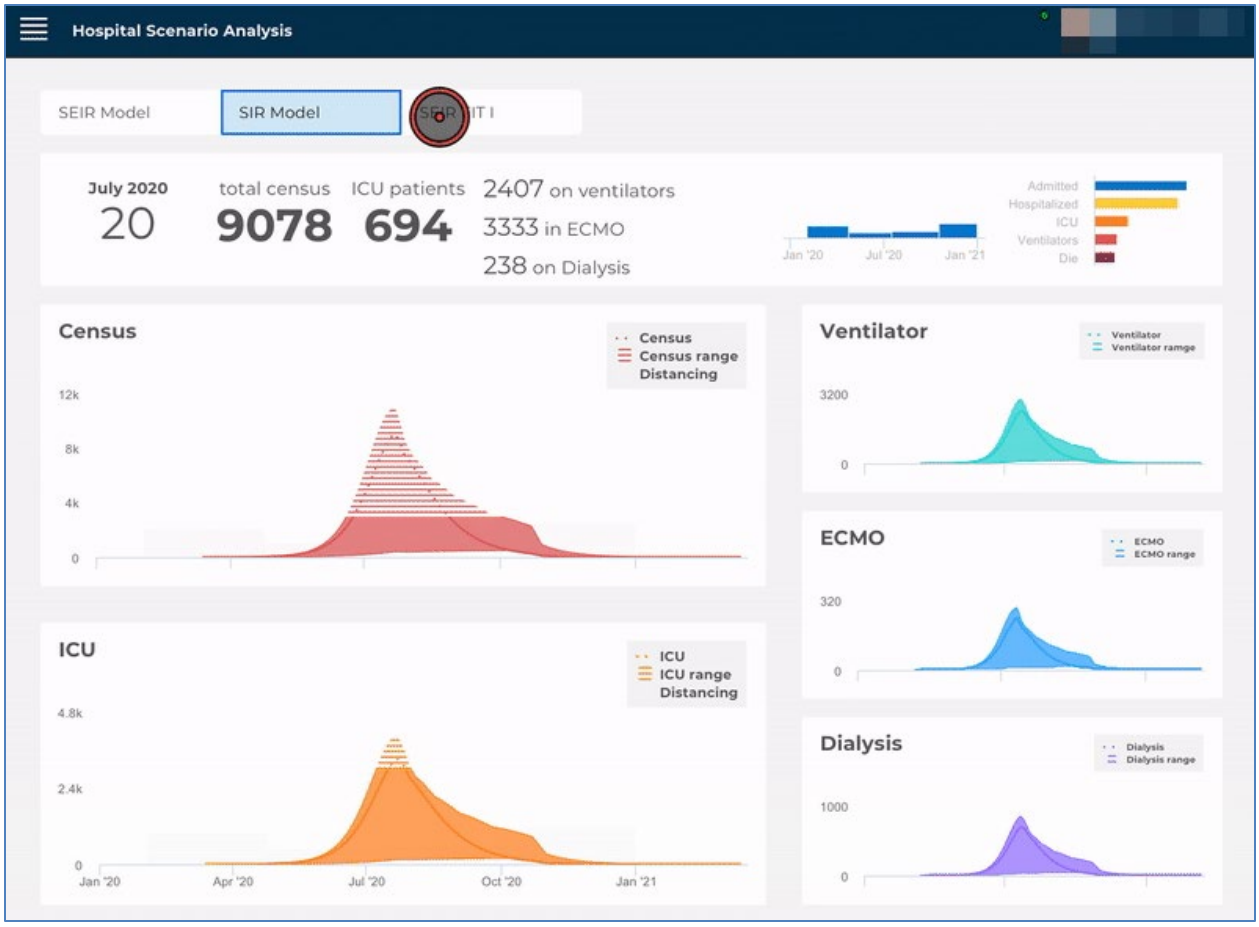

Figure 8. SIR (Susceptible-Infected-Recovered) MODEL.

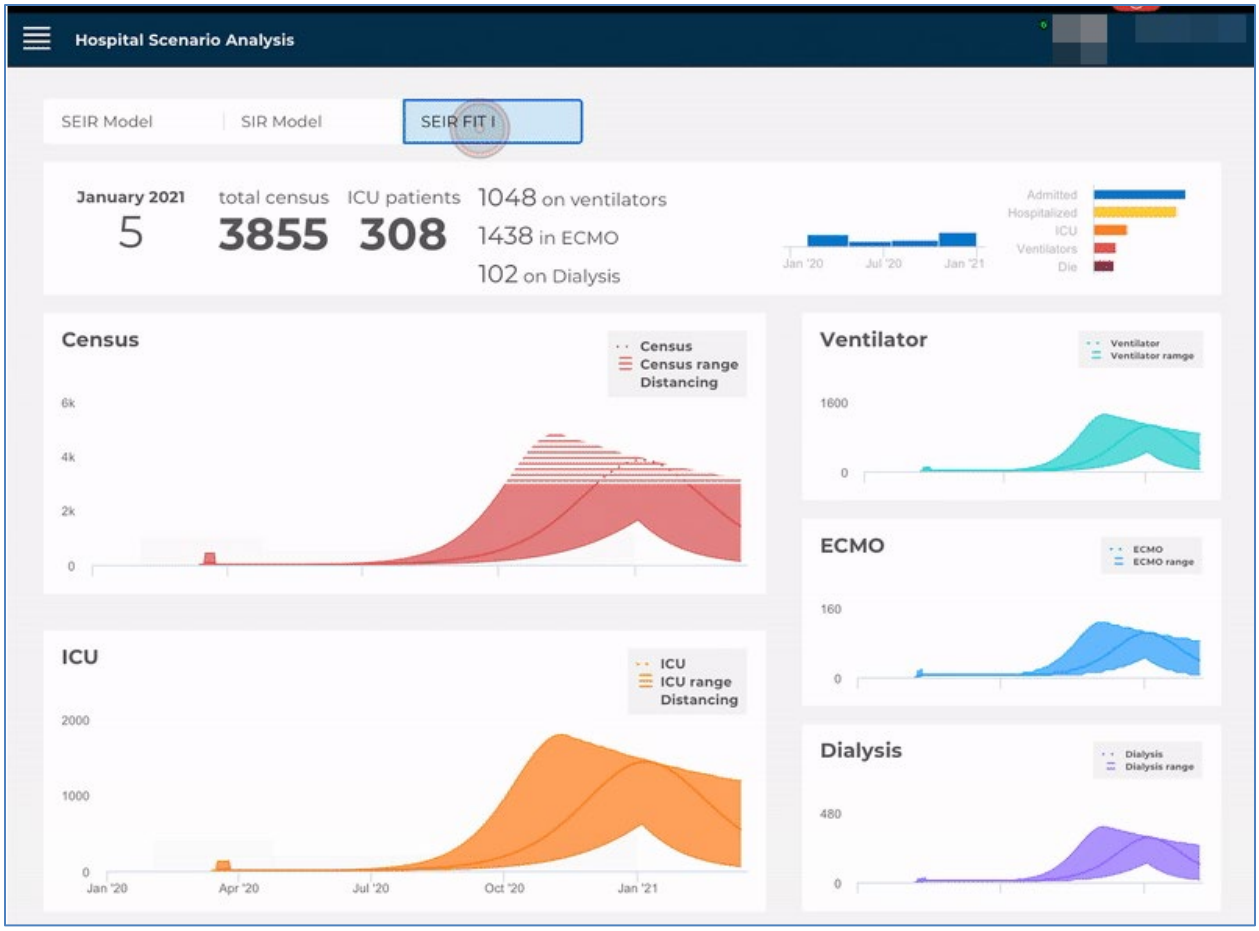

Figure 9. SEIR (Susceptible-Exposed-Infected-Recovered) FIT I MODEL.

ROADMAP AND FUTURE OF WORK

If building a simulation platform is not on a customer roadmap, it could impact their ability to conduct experiments based on real-world situations. Furthermore, it could potentially impact their ability to predict, describe, explain, and investigate the behavior of new situations as they arise.

Customers who plan on creating simulation platforms, based on the above example either in the healthcare, life sciences, or supply chain industry, can take advantage of a simulation model to conceptualize complex and real-world situations into a simplified form. As per Munsaka and Carniello, simulation modeling should account for both deterministic and stochastic considerations. It should also allow for the quick and responsive synthesis of data within a system and facilitate deeper insight into the KPI that you are researching, thereby optimizing the overall design and plan.

Within the clinical trial simulation example, a platform to model an enrollment “rescue” plan to get the trial back on track while also understanding cost/timeline with greater clarity is valuable. Such a platform can be created by using simulation and optimization to provide an ensemble of outcomes to quantify risk and minimize time to the target value for patient enrollment. This would be of tremendous value for clinical research organizations and pharmaceutical companies to improve their decisioning for in-process clinical trials by predicting future patient enrollment based on the current state of the trials in progress. Furthermore, the risk of falling behind on enrollment and budget constraints would be mitigated by optimizing the selection of site activation as the clinical trial progress. The problem formulation underlying the creation of such a platform is a multi-step stochastic optimization problem. It recommends the best courses of action to take over time as the uncertainty is resolved in multiple stages. Through artificial intelligence, the action can be further automated. Additionally, the foundational technology can be used to develop and manage adaptive

clinical trials. In comparison to the enrollment planning case study of the previous section, adaptive clinical trials would move away from a one-size-fits-all approach to allow for more patient centric, tailored therapies. The goal of an adaptive clinical trial is to provide the right patient with the right drug at the right time.

CONCLUSION

This paper highlights simulation design platform methodologies, deep dives case studies, while reviewing intricacies and challenges behind working on simulation-based design platforms. It also provides a brief review of the current state of simulation and summarized roadmap of future trends in creation and development of simulation design platforms. As stated per Hummel J, Wang S, Kirkpatrick J., successful simulation outcomes do not guarantee a successful path, but they can significantly improve decision making.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

Pritesh Desai
SAS Institute Inc
Pritesh.Desai@sas.com

Allison Sealy
SAS Institute Inc
Allison.Sealy@sas.com

Shawn Tedman
SAS Institute Inc
Shawn.Tedman@sas.com

Lois Wright
SAS Institute Inc
Lois.Wright@sas.com

Bahar Biller
SAS Institute Inc
Bahar.Biller@sas.com