# Taking Personalized Medicine Mainstream: Unlocking the Potential of Patient Data with Business 4.0™


## Abstract

Personalized medicine is poised to impact both patients as well as the healthcare ecosystem in ways that were unimaginable even a couple of decades ago. Personalized medicine involves taking treatment decisions and administering precise drugs for an illness - based on patients' clinical and personal characteristics including their genomic, microbiomic, and epigenetic profiles. Effective delivery of personalized medicine will ensure disease management by default, through continuous monitoring of treatment outcomes aimed at enabling right clinical decisions.

To realize such a model, a connected healthcare ecosystem comprising providers, payers, life sciences organizations, and technology companies is essential. All stakeholders must contribute to care management and coordinate by leveraging integrated patient data for clinical insights. The ecosystem needs to be supported

by technology platforms underpinned by Business 4.0™ drivers i.e. artificial intelligence, agility, automation, and cloud, to create the fundamental building blocks of personalized healthcare in practice. The platforms enable seamless integration and analysis of patient data, and use scalable, intelligent, cognitive systems to drive insights from the data and create a framework that can deliver mass personalization.

The paper presents a model for the future of healthcare and identifies three types of core platforms needed to build a connected healthcare ecosystem in order to deliver personalized medicine effectively and efficiently.

# Personalized medicine: Improving treatment outcomes and overall care management for patients

According to the 2017 progress report from FDA[1], more than one in four drugs approved by the agency over the past four years is a personalized medicine. The report also emphasizes that there is a strong focus on leading healthcare away from one-size-fits-all medicine toward the utilization of molecular information to improve outcomes. As of September 2018, there are 356 pharmacogenomics markers published in drug labels on the FDA website, of which more than 30% are related to Oncology[2]. While the life sciences industry is continually improving the methods for enabling scientific discoveries and developing personalized drugs and biomarkers, this is still a small subset of overall drugs and treatment protocols practiced in medicine today.

To enable mass personalization of healthcare, new evidences need to be generated by collating vast amounts of patient data across clinical practices. At the moment, such critical data is not leveraged in the life sciences industry. The lack of availability of patient data, particularly health outcomes under specific treatment plans, poses challenges to life sciences organizations in discovering personalized drugs and biomarkers. Hospitals need to actively track the outcomes of therapies administered to each patient through disease management and leverage this data for translational research in collaboration with life sciences organizations. Although health payers are involved in disease management, it is limited with the objective of reducing costs. Some of the research-centric hospitals, particularly those related to cancer, are involved in translational research, but the practice is not widespread. Such initiatives are also lacking in other specialties.

Life sciences organizations need to take the lead by forming a consortium with governments and research hospitals to collaboratively perform translational research. Hospitals can help monitor whether the health outcome of a patient to a particular therapy is different from the expected pattern during the disease management phase. If there is an unexpected

outcome, the patient data should be studied further to understand why the therapy led to poor outcomes or adverse events. Through subgroup level analysis of patients with similar characteristics, researchers can identify patterns in the data to generate new evidences and discover biomarkers from specific patient cohorts. To develop a connected healthcare ecosystem, these evidences should be made available to the physicians at the point of care to help them make the best decisions on specific, personalized therapies for patients with unique characteristics.

## Key obstacles in delivering personalized medicine

To realize the true potential of personalized medicine, the entire healthcare ecosystem must be transformed and geared to deliver patient-centric treatment strategies at the point of care. However, creation of such an interlinked ecosystem is challenging as currently medical information systems operate in silos, and healthcare providers are deprived of insights to personalize treatment because of lack of data on patient characteristics and their response to specific treatments.

Since healthcare systems used for disease management do not rigorously track patient intervention and health outcome data in the clinical setting, the data required for translational research is currently unavailable or is available only in a limited context. What's more, they are not leveraging large volumes of patient data available at the point of care. The delivery of personalized medicine is further hampered by the absence of AI-driven systems that can mine patient data for optimized clinical decision making. Such systems can support physicians in reviewing patient-specific information, combine them with information from translational research, and provide insights for personalizing therapies.

This presents three key questions: How do organizations visualize a model framework to deliver personalized medicine? What are the types of platforms needed to deliver the model? How will organizations develop this ecosystem and drive the development and deployment of such systems?

Let's take a deep dive to find the answers to these questions.

## Envisaging a model framework to deliver personalized medicine

In addition to targeting a drug for specific patient populations, a personalized medicine framework would require ongoing analysis of patient characteristics and information on how patients with similar characteristics respond to specific treatments. The framework to deliver personalized medicine must therefore encompass the following functions:

- Collection of high quality and accurate patient data through digitized disease management protocols that involve constant tracking of interventions and patient outcomes in day-to-day clinical settings. This data can then be used for translational research to assess the treatment effectiveness, evaluate options to further personalize the therapies, and improve personalized medicine guidelines based on the new evidence generated. The insights can also help life sciences organizations pursue new directions in the discovery of novel drugs and biomarkers.
- Physician access to data-driven insights and evidences generated from translational research to support clinical decisions and personalize patient therapy. In this case, doctors need the assistance of AI-driven systems for clinical decision making, because of the multidimensional nature of patient data involving unique patient characteristics and complex rules that lead to personalized therapies.

Ultimately, all the systems and processes in the ecosystem must operate in conjunction - including systems for disease management, generation of useful clinical data, translational research using the data, as well as interpretation of translational research-based insights and their application in clinical practice.

## Delivering on the promise of personalized medicine: Types of platforms needed

To function efficiently, the integrated personalized medicine delivery framework must harness platforms that leverage digital technologies including AI, cloud, Big Data, advanced analytics, and Internet of Things (IoT) to constantly generate and apply new evidences and insights in clinical practice. Three such platforms that can help the organizations deliver on the promise of personalized medicine are shown in Figure 1.

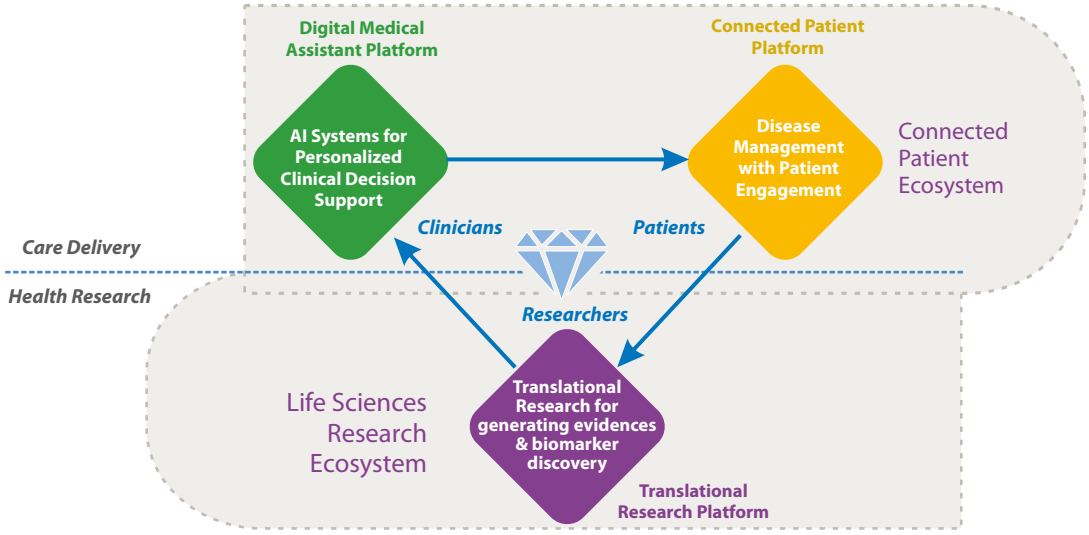


**Figure 1: Three interlinked platforms needed to deliver personalized medicine**

- **Digital medical assistant platform:** The digital medical assistant platform is essentially an AI-based expert system that supports data-driven and evidence-based clinical decision making by physicians, helping them select personalized therapies. This cognitive platform encapsulates clinical guidelines and associated medical knowledge while constantly learning from patient data and enriching the knowledge base, using various data-driven discovery techniques - including machine learning algorithms. The treatment protocols from the DMA platform are then fed into the connected patient platform for disease management and health outcome tracking.
- **Connected patient platform:** The connected patient platform ensures systematic disease management through patient engagement - monitoring of dosage adherence, remote management of treatment, and tracking of health outcomes. The system collects patient data, which is in turn, enriched with contextual information is passed on to the translational research systems. This platform can help in implementing a paperless and self-managing medication

process, enabling personalized patient support and interactive communication, and tracking outcomes and adverse events systematically.

- **Translational research platform:** The platform ingests patient data and uses it for translational research to generate evidences, and discover new biomarkers. The translational research platform:
  - Assimilates clinical and non-clinical data such as molecular and imaging data in an integrated database. It also integrates with genomics and multi-omics databases to select right patient cohorts according to specific characteristics.
  - Provides molecular data analysis capabilities to enable bioinformatics analysis and create patient-specific molecular information, and finally, meshes the information with the clinical information.
  - Automates clinical evidence generation process through the data-driven discovery by intelligent mining of integrated clinical, molecular, imaging, and other types of patient data.

In essence, the three platforms empower the healthcare ecosystem to deliver personalized medicine at the point of care.

## Embracing Business 4.0™ to take personalized medicine to the next level

At a time when patient expectations and regulatory demands are intensifying, generalized evidence-based treatment guidelines can lead to too many or conflicting therapies. It is increasingly important to develop frameworks and systems to continually enrich existing evidence-based practices with novel insights from translational research, to identify which treatment strategies and targeted therapies work best for which set of patients. Forward looking organizations that adopt a disruptive approach to patient-centric care - one that combines innovative research paradigms with qualitative analysis using next-gen technologies – will garner competitive advantage through effective discovery and delivery of personalized medicine.

## References

1. Personalized Medicine Coalition, Personalized Medicine at FDA, December 2017(accessed October 2018), http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM_at_FDA_2017_Progress_Report.pdf

2. USFDA, Table of Pharmacogenic Biomarkers in Drug Labeling, March 2018(accessed October 2018), https://www.fda.gov/Drugs/ScienceResearch/ucm572698.htm

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