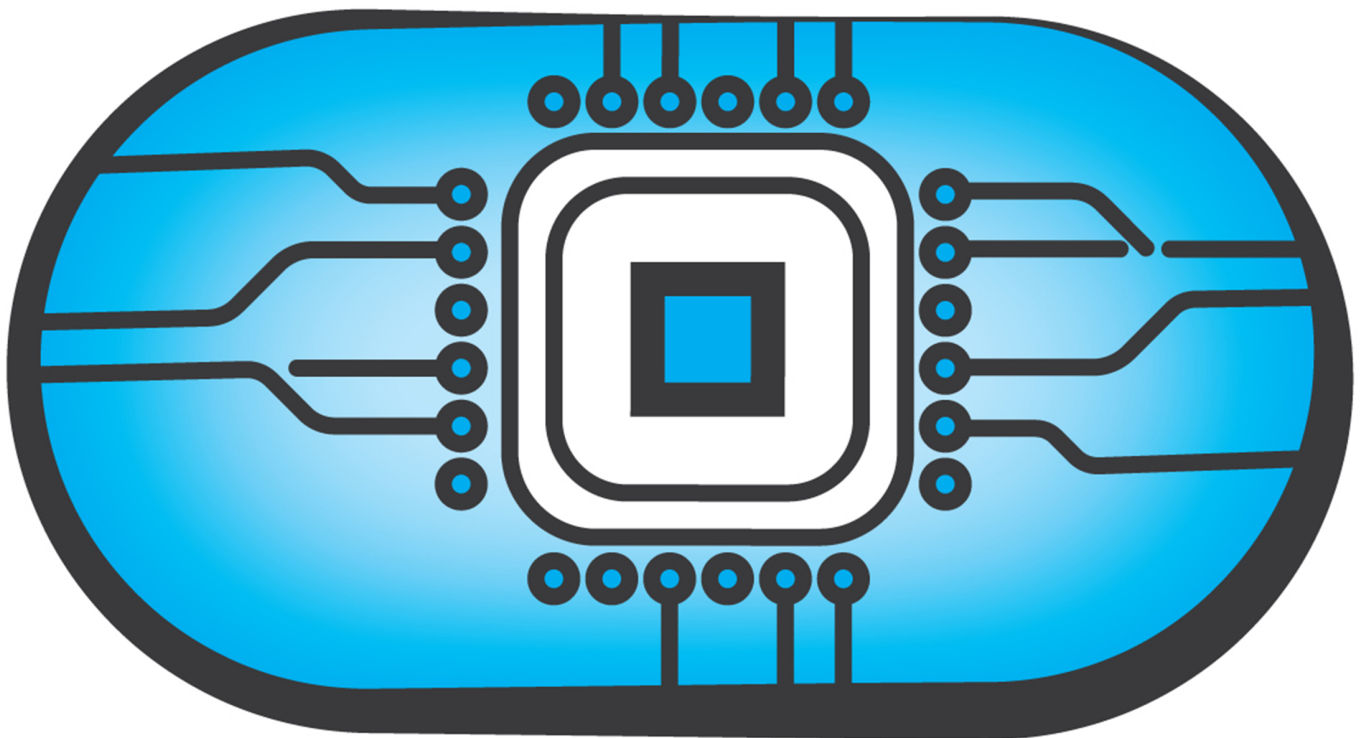


Smart integrated Medicine or S[i]M



KANSAL & COMPANY
— COURAGE TO LEAD —

INSIGHTS

All industries in the U.S. are experiencing unprecedented levels of disruption and change and are broadening their definitions of innovation as a basis of competition. Yet biopharmaceutical innovation remains narrowly focused on the biopharmaceutical product.

As a result, the industry is facing significant downward pressure on its earnings, and the business model is beginning to unravel. Key factors accelerating this decline include:

- ◆ Limited white spaces for traditional product-focused innovation
- ◆ Therapies versus cure
- ◆ Slow transition from old to new technology
- ◆ Outcome & Value vs. Safety & Efficacy
- ◆ Commoditization
- ◆ Consumerism
- ◆ New disruptors
- ◆ Evolution of Regulatory Policy

However, the CEO agenda continues to stay focused on sustaining the historical business model versus redefining it. As a result, there is constant restructuring and reorganization of companies in the industry and the profit pools continue to shrink.

The industry needs to rethink what innovation means to meet the modern healthcare consumer where they're at. We propose expanding CEO agenda to broaden their role in healthcare ecosystem beyond the suppliers of biopharmaceuticals. Industry's core competencies in understanding of disease mechanisms and data-driven solutions positions it well for such a future.

Biopharma industry perfected the art of monetizing customer data, long before Facebook, Google or Amazon. Industry should look at how it can broaden its relationships with patients and corresponding role in the healthcare ecosystem leveraging its data capabilities.

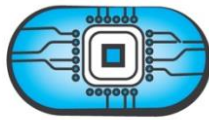
Smart [integrated] Medicine allows the industry to harness its core competency in understanding of disease to build direct relationships with patients.

Smart integrated medicine is the next generation of healthcare technology. It's any medicine that is a combination of a chemical molecule/biologic and a digital chip/other digital technology capable of capturing and transmitting data related to body's physical, chemical or biological processes.

Smart integrated Medicine (S[i]M) could come in many forms. It can be implanted in the body, ingested orally, delivered via infusion, inhaled, applied topically to the skin, or be digitally delivered in absence of a biopharmaceutical product (but still requires significant human involvement to exert its fullest effect).

RKJH 2017 Standard defines levels of "Smart" features in S[i]M that can enable manufacturers, regulators, payers, providers and patients to create approval, administration and reimbursement policy frameworks and drive S[i]M's adoption and evolution. You can read more in our [book](#).

A stepwise transformation is the pragmatic approach to building such a future. Companies that successfully adopt this model will be winners in the healthcare of the future.



SMART THERAPEUTICS

RKJH 2017 Standards to define levels of “smart” features in therapeutics that can enable manufacturers, regulators, payers, providers and patients create approval, administration and reimbursement policy frameworks and drive evolution of “smart therapeutics.” – © Ruchin Kansal & Jeff Huth. 2017

Level 0: No Automation

Smart Capability: None.

Provider involvement: Prescribing & administering.

Patient Involvement: Taking medication.

Manufacturer Involvement: Pharmacovigilance through spontaneous reporting.

Examples: All self-administered prescription products.

Level 1: Passive Medication Adherence

Smart Capability: Passive Medication Reminders.

Provider involvement: Prescribing & administering.

Patient Involvement: Taking medication.

Manufacturer Involvement: Pharmacovigilance, adherence messaging and monitoring at population level.

Examples: Smart Pill Bottles & Dispensers

Level 2: Active Medication Adherence

Smart Capability: Ingested Medication Reminders that alert patients when medicine concentration falls below a threshold within the body.

Provider involvement: Prescribing & administering.

Patient Involvement: Taking medication.

Manufacturer Involvement: Pharmacovigilance.

Examples: Otsuka & Proteus Technologies combination product (Abilify + smart chip)

Level 3: Assisted Dosing

Smart Capability: Ingested Medication alerts patients and providers when medicine concentration falls below a threshold within the body, side effects and clinical efficacy and effectiveness.

Provider involvement: Prescribing, administering., monitoring and adjusting.

Patient Involvement: Taking medication and active engagement with provider.

Manufacturer Involvement: Enable Patient Provider Dialog. Active Recommendations. Pharmacovigilance.

Examples: None

Level 4: Smart Dosing

Smart Capability: Controlled release of ingested medication concentration based on real-time monitoring of side effects, clinical efficacy and effectiveness.

Provider involvement: Prescribing, administering, monitoring and adjusting.

Patient Involvement: Taking medication.

Manufacturer Involvement: Enable Patient Provider Dialog. Active Recommendations. Pharmacovigilance.

Examples: None

Level 5: Healthy Time

Smart Capability: Guarantee of healthy time through active , remote management.

Provider involvement: Part of manufacturer service.

Manufacturer Involvement: Enable Patient Provider Dialog. Active Recommendations. Pharmacovigilance.

Patient Involvement: Taking medication.

Examples: None