

Conclusion

Traditional reliance on peer-reviewed empirical science has resulted in several health and environmental issues, and forced companies to operate outside of their preferred risk profiles. To address the increasing complexity in Life Sciences and related industries, executives should ponder a number of questions:

- How does your organization address the increasingly complex and uncertain environment of discovering new science and proving that it works?
- How do you evaluate the validity of scientific claims of potential partners, collaborators or acquisitions?
- Are your existing empirical testing methods sufficient to meet current and future regulatory, safety, and efficacy requirements?
- Can increased evidence of value create differentiation, eminence or competitive advantage for your products or organization?

By exploring new business models that set independent verification as a key part of scientific research, executives and regulators can realize more value from R&D, confirm the reliability of scientific claims, reduce associated business risks, and facilitate evidence-based policy making.

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Systems Biology Verification

Setting the scene for scientific auditing



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For executives and regulators in the Life Sciences industry, research and development (R&D) has become progressively more complex and harder to manage – making it difficult for traditional research protocols to keep up. Peer review has come up short in identifying inaccuracies in scientific claims – a problem that can lead to severe consequences. New models can help increase the value of R&D, improve the reliability of scientific claims, drive better business decisions, and mitigate risks.

An independent, systematic approach

Systems Biology Verification (SBV) – see figure – is an independent, systematic approach for verifying research processes, methods and data, and extrapolating scientific outcomes to identify mid- to long-term effects sooner. SBV utilizes multidisciplinary research, mathematics and computational power to develop libraries of models, methods and data, which are then used by an independent body – a scientific auditor – to assess and extrapolate the validity of research outcomes. SBV relies on a proven verification methodology and expert consulting services to help assure objectivity and confidentiality – along with the necessary tools to conduct the verification.

SBV allows organizations to:

- **Assess methods and data**
 - *Benchmark methods or models* on an unseen dataset using a new form of peer review, distinguished by an in-depth, fully independent and transparent process
 - *Verify empirical data* through the application of a range of different models and methods, and the consolidation of multiple sources of data.
- **Evaluate safety and efficacy** using proven predictive models and data, as well as long-term, cumulative and environmental impacts. This assessment can be used for:
 - *Advanced target identification*
 - *Innovative study design*
 - *Optimized candidate selection*

- *Outcome-based solutions*
- *Science repurposing*
- *Effective R&D strategy*
- *Integrated health and environmental safety assessment.*

- **Provide evidence of value** through an external audit of evidence to support traditional clinical data in regard to safety and efficacy. This can be used for:
 - *Comparative effectiveness* to drive growth in pricing, market size and market share
 - *Regulatory claim complement* to support traditional research in terms of reliability; evaluate long-term, cumulative or environmental effects; specify patient groups, and/or optimize dosage
 - *Due diligence* for mergers and acquisitions or licensing deals. SBV can help organizations verify the value of a compound or technology prior to acquisition.

Understanding the benefits

SBV can be of value to industries, policy makers, research institutions and non-profit organizations in sectors such as Life Sciences, Healthcare, Consumer Products (for example, Nutrition, Veterinary, Tobacco) and Energy, among others, by:

- Increasing the value of R&D by identifying potential problems early on and improving success rates at later stages. (We foresee SBV to be particularly valuable early in the R&D process).
- Reducing the risk in strategy development, and when performing due diligence for mergers and acquisitions, alliances or licensing.
- Opening new revenue streams by providing evidence of value, such as that from diagnostic kits.
- Avoiding potential litigation costs and reputation damage by identifying potentially harmful effects.
- Facilitating evidence-based health and environment policy making by complementing the information submitted by companies, and providing an additional verification step in the regulatory process.

