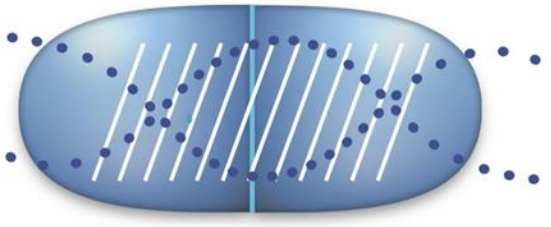

STRIPE

STANDARDIZING
LABORATORY
PRACTICES IN
PHARMACOGENOMICS

STRIPE

An ASP Initiative

The American Society of Pharmacovigilance (ASP) is a 501(c)(3) nonprofit organization. ASP is a national biomedical and healthcare network with membership open to all healthcare professionals. ASP's mission is to rapidly and dramatically reduce the high rate of suffering and mortality due to adverse drug events in the US.

A Collaborative Community

The Standardizing Laboratory Practices in Pharmacogenomics (STRIPE) Collaborative Community was formed in 2020. The purpose of the STRIPE Initiative is to bring together pharmacogenomics stakeholders in a continuing forum of private- and public- sector members, including FDA, to achieve common outcomes, solve shared challenges, and leverage collective opportunities.

The mission of STRIPE is to accelerate the development of personalized medicine practices as a standard of care by uniting patients, providers, industry, regulators, payers, and other key stakeholders. The community seeks to harmonize and optimize standards, practices, and resources related to pharmacogenetics testing that will improve access to safe, accurate, and reliable information about a patient's medication and drug-gene interactions.

Core Values

1. Participation is open to all stakeholders in the field of pharmacogenomics.
2. Members represent their larger communities.
3. Trust will be fostered through transparency.
4. Objectivity will be of highest importance.
5. The community will be a catalyst for positive change in research.
6. The community serves as a mechanism for cross-sector communication.

STRIPE

Steering Committee

The Steering Committee has been established to pioneer STRIPE and to set strategic and operational goals relating to STRIPE which will guide its movement and advancement. Members of the Steering Committee will be responsible for representing and securing buy-in among stakeholders and their larger communities on the direction of STRIPE. STRIPE will convene this Committee to provide guidance and input to accomplish community objectives.

Advisory Board

The Advisory Board is comprised of delegates, one from each of nine subcommittees representing key interests central to the standardization initiative. The board serves to summarize subcommittee activities and advise on the direction and priorities of the community. Advisory Board members chair or co-chair their respective subcommittee.

Subcommittees

Technology Subcommittee

The Technology Subcommittee has been proposed to ascertain and evaluate key determinants of variation in laboratory accreditation processes, performance and technical specifications, limitations of systems and rules governing commercially available analytic methods and testing platforms used for pharmacogenetics testing.

Regulatory Affairs Subcommittee

The Regulatory Affairs Subcommittee has been established to assess regulatory, rulemaking and guidance pathways for pharmacogenomic tests. The subcommittee will also identify opportunities for statutory or regulatory reform to reduce regulatory burden and duplication, and to streamline commercialization pathways for pharmacogenomic tests to reach patients.

Evidentiary Standards Subcommittee

The Evidentiary Standards Subcommittee has been established to recommend common evidentiary standards for analytical and clinical validity --using valid scientific evidence --across all stakeholders and to ensure ongoing development of pharmacogenetic tests, including through the use of real-world evidence and real-world data.

Information Systems Subcommittee

The Information Systems Subcommittee has been proposed to establish and develop project-based tools and assets for the STRIPE community and all stakeholders, including the architecture, management, assembly and visualization of public-, private-, and open-access data sets; real world evidence, real world data and community-generated data for the benefit of all stakeholders.

STRIPE

Subcommittees, Continued

Clinician Affairs Subcommittee

The Clinician Affairs Subcommittee has been proposed to identify structural barriers to the adoption of pharmacogenetics testing and ascertain key determinants of variation in clinical utilization, including challenges relating to the ordering, interpreting and delivery of test results

Patient Advocacy, Access & Equity Subcommittee

The Patient Advocacy, Access & Equity Subcommittee has been proposed to assimilate knowledge, empathy and understanding of the patient experience and journey to highlight gaps in pharmacogenomics literacy, patient engagement and access to treatment.

Communications Subcommittee

The Communications Subcommittee has been established to design and implement a high-impact, uniform messaging and communications strategy for STRIPE members and stakeholders. The subcommittee will develop relationships with a diverse global network of key opinion leaders, journalists, reporters, publishers, event organizers and other media contacts.

International Affairs Subcommittee

The International Affairs Subcommittee has been proposed to unite an international network of key stakeholders in pharmacogenomics and identify opportunities to align global standardization efforts.

Consensus Development Subcommittee

The Consensus Development Subcommittee has been established to design and architect methodologies for enhancing consensus-based recommendations, including patient, provider, laboratory, technology and clinician standards in pursuit of improved cooperation among stakeholders in pharmacogenomics. This effort will incorporate knowledge about current standards and be collaborative with relevant outside organizations so as not to duplicate standards.

General Committee

The General Committee has been established to provide an open forum to all stakeholders in pharmacogenomics to engage in the development of consensus-based industry standards and collaboration to generate evidence that may dramatically increase access, lower costs and improve patient outcomes relating to pharmacogenetics testing.

Study Design Task Force

The purpose of the Study Design Task Force is to provide high-level recommendations, tools and resources regarding pharmacogenomics study methods to optimize the regulatory and clinical utility of pharmacogenomics research.

STRIPE

Current Members

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Access Dx
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Alva10
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Members are listed by affiliation, current as of October 2022.

STRIPE

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Kandace Schuft

Members are listed by affiliation, current as of October 2022.

STRIPE

Sustained Engagement

STRIPE continues to develop a common agenda for addressing challenges in pharmacogenomics and personalized medicine to achieve its aim of large-scale change: a performance measurement system, mutually reinforcing activities, and enhanced communication channels. Together, members will guide vision and strategy, support activities, establish shared measurement practices, build public will, advance policy and mobilize resources.

Shared Measurement System

STRIPE will develop a list of indicators that determine how success will be measured and reported. This includes but is not limited to quality measurements, performance measurements, safety measurements and value-based measurements. This establishes a basis for assessment and reassessment processes as stakeholders implement its activities and sets the stage for ongoing course adjustments.

Continuous Community Development

STRIPE is built to last. Every member counts. The community will grow and prosper over time by creating and nurturing a vibrant ecosystem of ideas, perspectives and people. Community-development activities are deliberate, goal-oriented and purpose driven. The community is driven by scientific inquiry, skills, capabilities and competence to advance the STRIPE mission. The Steering Committee, Subcommittees and General Committee provide ongoing opportunities to magnetize talent, encourage new member involvement and discover new opportunities for focus and attention on pressing issues and concerns. This does not, of course, require that all members do the same things. There are nine pathways for participation, incorporating various levels of involvement which enable systematic growth. There is no limit on members or participation, and this allows flexibility in determining new pathways for participation in the future.

Organizational Learning

The community will continuously seek and explore how pharmacogenomic information can be effectively and efficiently delivered to patients and clinicians for improving care. This includes creating and implementing new ways of thinking and translating research and evidence into actionable clinical guidelines, protocols, care pathways and opportunities to improve patient outcomes across the entire pharmacogenomics value chain. Over time the community will build and grow an invaluable portfolio of assets enabling knowledge-generation and organizational learning that may rapidly diffuse among health care systems, physicians and patients, enabling a positive feedback loop and rewards-based system for breakthroughs, thus encouraging more innovative thinking.

Shared-Valued Generation

The community will pursue success in a way that yields societal benefits through collective impact that will benefit all stakeholders in pharmacogenomics. The Initiative will advance progress and create new and unimagined economic, clinical and medical opportunities for improving patient outcomes, and making the safety and effectiveness of pharmacogenetics testing sound science.

STRIPE

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