

The Safety Intelligence Program

Building a Global Safety Solution

The screenshot displays the BioWisdom Safety Intelligence Program interface. At the top, it shows the search results for the terms 'abacavir; telmisartan; telithromycin'. The main content is a table with columns for Term 1, Relationship, Term 2, Species, Tissue, and Evidence. The table lists various interactions and effects, such as Telithromycin inducing Hepatocyte Damage and Abnormal Liver Function, and Telmisartan increasing Alanine Aminotransferase Level. To the right, there is a 'Chemistry structure search' panel with a search bar and a 'Search' button. Below the search bar, there is a chemical structure diagram of a compound, likely Telmisartan, with its SMILES string: Cc1ccc(cc1)N2C(=O)N(C2)c3ccc(cc3)C4=CC=CC=C4. The interface also includes navigation links like 'Main', 'My SIP', and 'My Account'.

Term 1	Relationship	Term 2	Species	Tissue	Evidence
Telithromycin	INDUCES	Hepatocyte Damage	human	Liver	EMA EPARs: levidas/101501eni6.pdf
Telithromycin	INDUCES	Abnormal Liver Function	human	Liver	EMA EPARs: levidas/101501eni6.pdf
Telithromycin	INCREASES	Lactic Dehydrogenase Level	human	Bodily Fluid, Blood	EMA EPARs: levidas/101501eni6.pdf
Telithromycin	INHIBITS	Cytochrome p450, Subfamily IIIA (nifedipine oxidase), other	human	Undefined Tissue	Internet: http://medicine.jub
Telithromycin	MAY CAUSE	Severe Hepatotoxicity	human	Liver	Medline: 16481451
Telithromycin	DECREASES	biliary clearance of doxorubicin	rat, Sprague-Dawley	Liver	Medline: 16377671
Telithromycin	INCREASES	Aminotransferase Level	human	Bodily Fluid, Blood	Show/Hide (2 records)
Telithromycin	IS SINGLE ACTIVE INGREDIENT IN	Ketek	human	Bodily Fluid, Blood	Show/Hide (14 records)
Telithromycin	HAS ACTIVE INGREDIENT	Telithromycin			CCIS: 590915
Telithromycin	IS ACTIVE INGREDIENT IN	Telithromycin			CCIS: 590915
Telithromycin	ELEVATES	Aminotransferase Level	human	Bodily Fluid, Blood	Medline: 16199242
Telithromycin	IS ASSOCIATED WITH	Mild Hepatotoxicity	human	Liver	Medline: 18159037
Telmisartan	INCREASES	Alanine Aminotransferase Level	human	Bodily Fluid, Blood	Show/Hide (2 records)
Telmisartan	INHIBITS	Reactive Oxygen Species Formation	human	Liver, Hep 3B	Medline: 17004092
Telmisartan	IS CONTRAINDICATED IN	Cholestasis	human	Liver	EMA EPARs: Micardis/19869
Telmisartan	INDUCES	Abnormal Liver Function	human	Bodily Fluid, Blood	EMA EPARs: Micardis/19869
Telmisartan	MAY CAUSE	Abnormal Liver Function	human	Liver	EMA EPARs: Pritor/198798e
Telmisartan	IS CONTRAINDICATED IN	Severe Liver Disease	human	Liver	Show/Hide (3 records)
Telmisartan	IMPAIRS	Hepatic Function Test	human	Bodily Fluid, Blood	EMA EPARs: Micardis/19869
Telmisartan	DOES NOT AFFECT	Liver Disorder	human	Liver	EMA EPARs: Micardis/19869

The Program

The Safety Intelligence Program (SIP) is an industry-sponsored strategic initiative that calls on the expertise of the pharmaceutical members and other key stakeholders to build the world's best intelligence resource for use in the practice of drug safety assessment.

The assessment of the safety profile of new and existing drugs remains a strategic priority for pharmaceutical companies and calls for a deep understanding of the mechanisms leading to the expression of adverse events. SIP emerges from the pharmaceutical industry's drive for a more systematic approach to harnessing past experience for the purpose of predicting risk in the future.

SIP is underpinned by powerful technology (including Sofia™) that creates a unique information format in the form of assertional meta-data*. Assertional meta-data represents a distillation of past observations pertaining to biological and chemical events reported in the scientific literature or other sources. Under the Safety Intelligence Program, assertional meta-data is generated from any electronic source irrespective of format (structured or unstructured), at scale and at high quality. The assertions are rendered consistent by the use of Sofia terminology and are uploaded into the Safety Intelligence System, which incorporates the leading data integration and search platform SRS. The Safety Intelligence System is made available through a simple Web-based interface to all members, enabling them to easily perform systematic analyses of the assertional meta-data, for the purpose of understanding the mechanisms of drug-induced adverse events.

The Program is powered by its members. These include the founding industry Charter members, for example AstraZeneca plc and Johnson & Johnson PRD, who provide an influential community to define the best practice in the use of information in safety-related decision-making.

The Mission

Working with the current Charter membership of SIP, we have defined a challenging mission:

- To ensure that the benefit/risk decisions made for every compound in the development pipeline or drug on the market is based on having visibility to the best information possible.
- By the year 2013, to eliminate those drug withdrawals that result from adverse events that could have been predicted.

* Example assertion: Acetaminophen INDUCES Hepatic Necrosis

Participation

There are two levels of participation

- **Membership** allows individual and groups of scientists to use the Safety Intelligence System in their global drug development activities.

Access to the Safety Intelligence System by individuals enables an organization to benefit from the unique format of assertional meta-data for their business activities.

Membership also provides access to the SIP Members Forum. The forum provides exclusive access to on-going debates, materials, SIP Board meeting minutes, and scientific analyses created using the data in the Safety Intelligence System. As the membership grows, this page will be migrated to a fully functioning forum where members can post questions and replies.

Scientists from the following disciplines would benefit from access to the Safety Intelligence System: computational chemists, discovery scientists, toxicologists/pathologists supporting drug development project teams, clinical safety and pharmacovigilance professionals.

Through gradual use and realization of business benefit, Membership can be upgraded to Charter Membership at any time.

- **Charter Membership** includes pharmaceutical companies committed to contributing strategically to SIP having an interest in both the underpinning technology and the science of the program.

Charter members influence the direction of the Program and the development of the Safety Intelligence System. Through their investment in resources to accelerate the growth of the assertional meta-data, Charter members retain perpetual rights to that data.

Charter members also participate on the SIP board. The board, chaired by Jack Reynolds, takes an outward facing role to influence the external community towards a common goal in improving drug safety assessment through the use of the Safety Intelligence System.

Charter Membership also enables an organization to understand the underpinning technology of SIP and consider how this fits with ongoing technology initiatives being pursued internally.

Summary of Benefits

	Charter Membership	Membership
Access to the Web-based hosted Safety Intelligence System for up to 50 named users	✓	
Access to the Web-based hosted Safety Intelligence System on a named user basis, with discounts for volume purchases		✓
Dedicated BioWisdom resources to generate assertions, aligned to member's business priorities. Resource allocation covers assertion generation, curation and project management	✓	
Perpetual non-exclusive rights to the assertional meta-data generated throughout the program	✓	
Dedicated server hardware and system for each member.	✓	
High availability infrastructure (24x7, >99%)	✓	✓
SIP Board representation	✓	
Access to the SIP Members Forum	✓	✓
Training on the use of the Safety Intelligence System	✓	✓
Support	✓	✓
Access to a programmatic interface	✓	
Access SIP assertions from internal systems	✓	

Program Co-ordination

Julie C. Barnes PhD is Chief Scientific Officer at BioWisdom. Julie spent 15 years of her early career at GlaxoWellcome, now GlaxoSmithKline, where she held several senior positions including Head of Neuroscience. Her experience in pharmaceutical R&D includes project leadership across for early discovery through to the design of early Proof-of-Concept studies and biomarker development. At BioWisdom, Julie and her Healthcare team work with members of the Safety Intelligence Program to influence and support the use of the System and ensure the utility and impact of the approach internationally. Julie sits on the Board of BioWisdom, and holds invited positions on several other advisory boards of private companies and academic institutions.

Jack Reynolds, DVM, of JAReynolds & Associates is an active consultant and Director of Center for Molecular Safety Sciences, The Hamner Institutes for Health Sciences. Jack spent 18 years with Pfizer Global R&D, most recently as Senior VP of R&D and Worldwide Head of Safety Sciences and Comparative Medicine. Jack the current chair of the Drug Safety Executive Counsel and chairman of the SIP Board. Over the years, Jack has been involved with PhRMA as Chair the Preclinical Leadership Steering Committee. He was the first chairperson of FDA's Nonclinical Studies Subcommittee, a Pharmaceutical Sciences Advisory Committee. He is the co-founder and past president of the Regulatory and Safety Evaluation Subsection of the Society of Toxicology, a member of the Board of Trustees and Vice President for the Toxicology Education Foundation. He was also a member of the Health and Environmental Sciences Institute Board of Trustees and a former member of the Board of Directors of the Toxicology Forum, where he is now on their program committee.

Contact Information

If you are interested in joining this global initiative we would like to talk to you. Please contact SIP@biowisdom.com or telephone +44 (0) 1223 874800.