

Predict™

In Silico Tox Service



Setting New Standards in Computational Toxicology

Predict™ is a leading edge, technology-enabled solution, delivered as a service. Predict™ combines powerful computation models and expert reviews to help organizations assess chemical safety more quickly, efficiently and comprehensively.

Leadscope, an Instem Company – Empowered to Serve

Predict™ leverages Instem's expertise in delivering technology-enabled services, powered by Leadscope's advanced informatics and prediction technology, and comprehensive database solutions, that help organizations around the world unlock valuable knowledge contained in both public and proprietary sources of research data. Our toxicity databases access well over 500,000 toxicology studies for more than 200,000 chemicals, enabling fast, accurate, defensible and regulatory-accepted predictions.

Now delivered as a service, Predict™ supports a variety of applications including the ICH M7 pharmaceutical impurities guideline, assessment of extractables and leachables, and classification and labelling.

Key Features that Deliver Powerful Benefits

The Predict™ service builds on the power of world-leading computational models and databases, combining them with expert scientific review, to deliver comprehensive, unbiased, high quality, regulatory-accepted assessments of chemical safety.

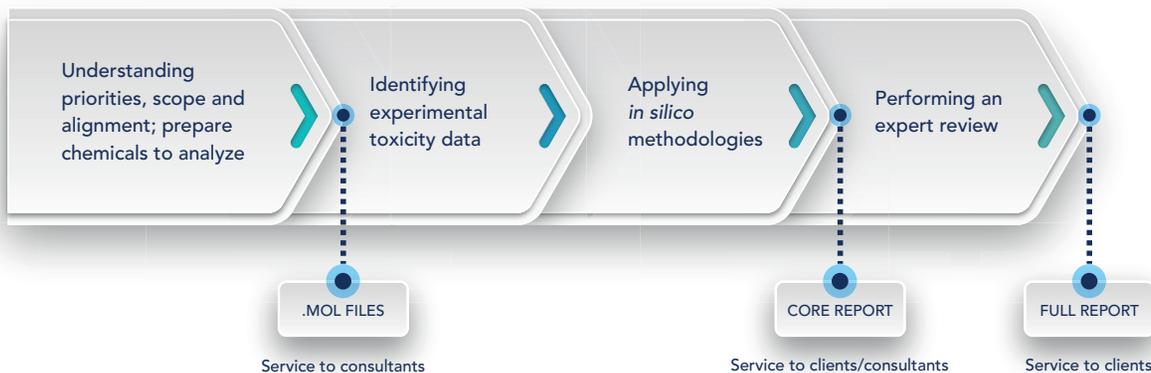
| Key Features of Predict™ | Key Benefits |
|---|--|
| Domain Experts Performed by expert scientists with vast experience in computational methodologies, toxicology, and chemistry. | Delivers high quality, scientifically robust assessments every time. |
| Comprehensive Approach Assessments leverage the latest information, including historical databases of toxicity studies. | Peace of mind that your assessments are always current and up to date. |
| Finely Tuned Process Assessments and expert reviews are based on a documented standard operating procedure. | Our standardized processes deliver confidence through comprehensive, consistent assessments time after time. |
| Actionable Information Our documentation summarizes the main conclusions, alongside detailed reports on data used and the prediction model results. | All assessments are completely transparent and fully documented enabling you to make clearer and quicker decisions. |
| Scalable The Predict™ service is cost effective and scalable for organizations of all sizes. | For organizations without the resources available to perform an expert review, Predict™ offers a complete (Q)SAR solution to satisfy regulatory requirements. For organizations with in-house expertise and technology, Predict™ can be used to augment existing capabilities or in times of peak demand. |
| Faster Turnaround Our experts will ensure we deliver what you need, exactly when you need it. | Quality assessments delivered on time, every time. Enabling you to make faster, better informed decisions. |
| Regulatory Guidance The Predict™ team has a deep understanding of applicable guidelines and regulatory agencies' processes. | Complete confidence that your assessments will be accepted by all of the key industry regulators. |

Supporting a Variety of Applications

| Service | Guideline or application |
|---|---|
| Mutagenicity (Q)SAR assessment | <ul style="list-style-type: none"> • ICH M7 pharmaceutical impurities • Veterinary medicinal products • Pesticide residuals |
| Paper-based purge arguments | <ul style="list-style-type: none"> • ICH M7 pharmaceutical impurities |
| Mutagenicity, Sensitization, and Irritation (Q)SAR assessment | <ul style="list-style-type: none"> • Extractables and leachables |
| Sensitization (Q)SAR assessment | <ul style="list-style-type: none"> • Dermal products (e.g., cosmetics, pharmaceuticals) • Chemical occupational exposure limits |
| Comprehensive* (Q)SAR assessment | <ul style="list-style-type: none"> • Generation of Safety Data Sheets <ul style="list-style-type: none"> • Occupational • Transportation • Cleaning • Occupational (banding derivation) • Evaluation of metabolites • Non-genotoxic impurities • Assessing product candidates • Assessment of excipients • ICH Q3A/B/C • ENDS |

* Cancer, mutagenicity, reproductive/developmental, acute, sensitization, irritation and organ toxicity

The Predict™ Process



Next Steps & Resources

To learn more, why not take advantage of our free, no obligation consultation and learn how Predict™ can help your organization assess chemical safety quickly, efficiently and comprehensively? Email us today at predict@instem.com to book your consultation with one of our *in silico* team.

Free Resource

Ask an Expert: Do you have any *in silico* questions? We encourage you to take advantage of this free industry resource by simply dropping an email to insilicoexpert@instem.com and one of our experts will respond ASAP and without any obligation.

InSilicoInsider

Visit our Blog: insilicoinsider.blog

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Flexible Options to Suit Your Needs

Clients can choose from the Core or Full Predict™ service option. With both options, clients no longer have to spend days searching and analyzing the data they need. Instem undertakes searches on multiple sources of data, performs regulatory-accepted *in silico* predictions and provides a summary of the results. With our Full Predict™ service, clients will also receive an expert review by a team of experts with deep knowledge of computation modelling, toxicology and chemistry.

| Deliverable | Full | Core |
|--|------|------|
| Relevant toxicity studies identified | • | • |
| Applicable <i>in silico</i> predictions performed | • | • |
| Full study and <i>in silico</i> reports included | • | • |
| Executive summary of data and predictions | • | • |
| Expert review of data and <i>in silico</i> results | • | |
| Expert reviewed overall assessments | • | |

From Concepts to Cures

A global provider of leading software solutions and scientific insight services, Instem is helping clients bring their life enhancing products to market faster. We enable organizations in the life sciences to more efficiently collect, report and submit high quality regulatory data, while offering them the unique ability to generate new knowledge through the extraction and harmonization of actionable scientific information.

Across the entire drug development value chain, every day Instem solutions are meeting the rapidly expanding needs of life science organizations for data-driven decision making, leading to safer, more effective products.

Instem supports its global roster of clients through offices in the United States, United Kingdom, France, Japan, China and India.

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