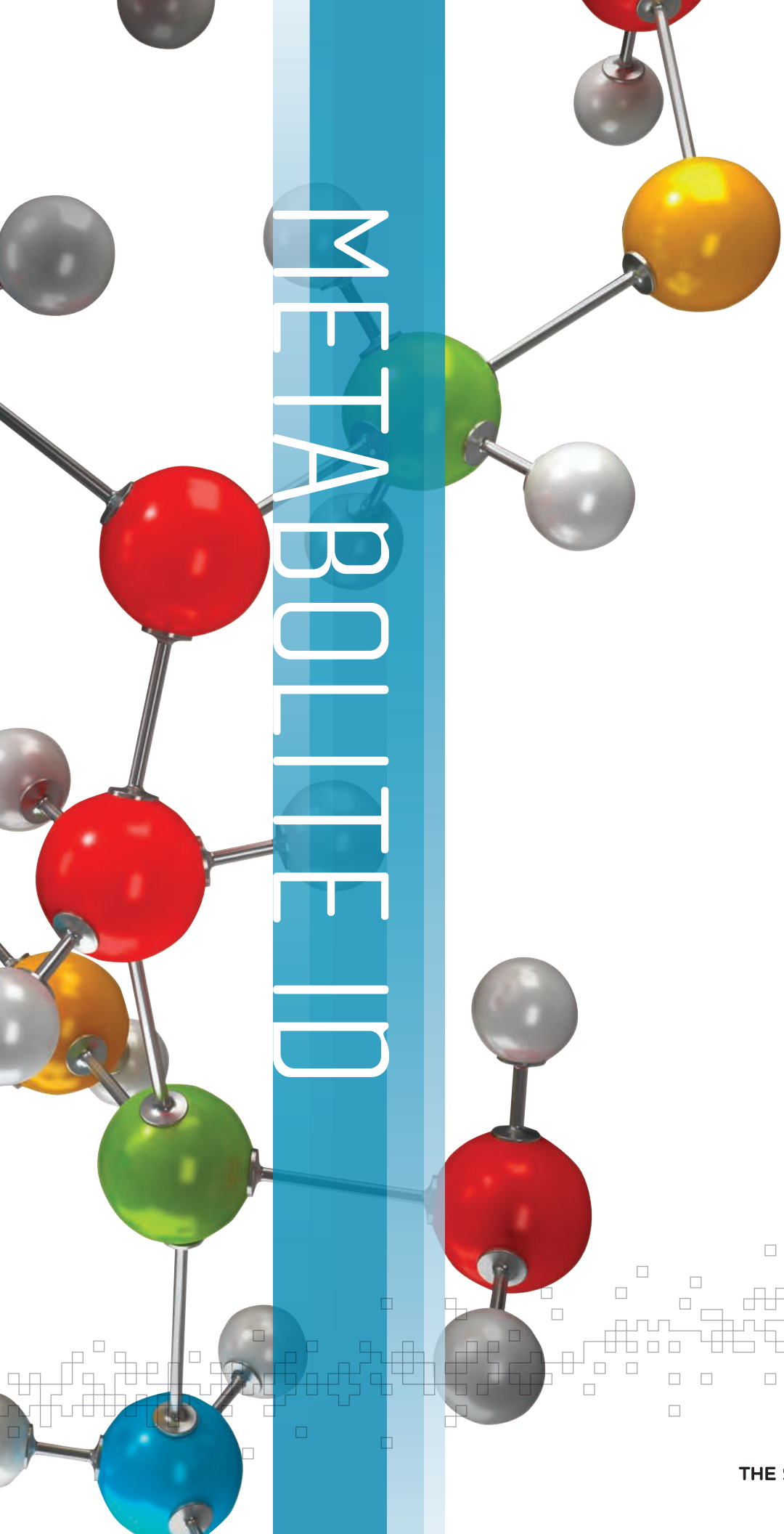
APPLICATION SOLUTION

METABOLITE ID

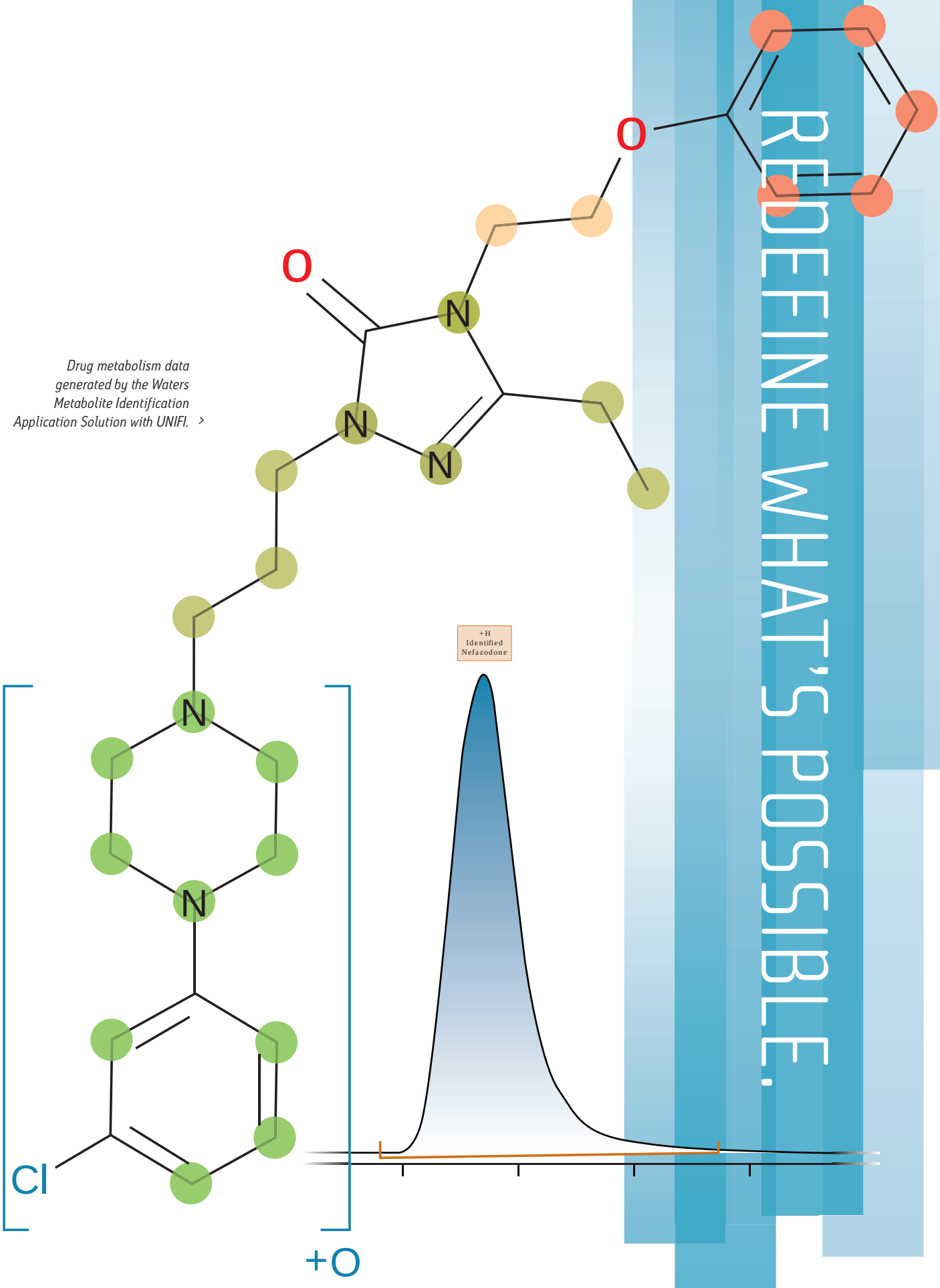


Waters

THE SCIENCE OF WHAT'S POSSIBLE.™

REDEFINE WHAT'S POSSIBLE.

Drug metabolism data generated by the Waters Metabolite Identification Application Solution with UNIFI. >



A next-generation application solution – developed for, and with, our customers.

All Drug Metabolism and Pharmacokinetics (DPMK) scientists working in Metabolite ID are looking for ways to reduce the time, resources, and labor required to accurately identify and characterize metabolites with the ultimate goals of developing new, innovative drugs faster. Progress has been made, but there is still clearly a need to further accelerate the timeline and enhance the quality of analytical results while keeping an eye on the financial bottom line.

As the cost of developing new drugs continues to escalate, repercussions are felt throughout the pharmaceutical industry. In discovery, there is greater pressure on scientists to identify potential problems in a drug candidate. In development, a more thorough understanding of metabolic fate and the safety implication of the drug are the imperatives. This means smarter, faster analyses are needed to find, identify, and confirm metabolites throughout the entire pipeline process. Understanding liabilities of a drug candidate earlier saves time and reduces costs significantly to benefit organizations in the long term.

This more confident, knowledge-driven approach to drug safety requires solutions that will continue to meet the mounting challenges of the future. Enter Waters.

Throughout our history, Waters has maintained a collaborative and enduring partnership with leaders in the Pharmaceutical and Life Sciences industry. Together, we have ceaselessly worked to develop and innovate solutions and technologies that will empower scientists – and help us all push the boundaries of what's possible.

The Waters Metabolite Identification Application Solution with UNIFI™ is the result of working closely with our customers around the globe for the last 12 years. Listening intently. Working with their laboratories. And leveraging knowledge and experience to develop the world's most powerful analytical platform for metabolite identification. The final product? An application solution that allows you to work more efficiently, confidently, and successfully than ever before.

Advancing the journey of a molecule.

IN DISCOVERY

Acquire knowledge and answers more quickly – allowing labs to proceed or change direction rapidly, and get the right molecules into the pipeline.

IN DEVELOPMENT

Get a far deeper understanding of the drugs you're working with – and ensure that the molecules are as well-characterized, and therefore as safe as possible.

KNOW MORE.
ACHIEVE MORE.

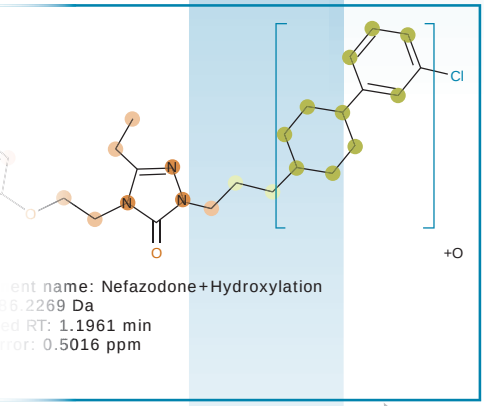
Doing more, better, and in less time is no longer a challenge – it's a solution.

Waters Metabolite Identification Application Solution with UNIFI is the world's most comprehensive metabolite identification system, assisting the biotransformation scientist, in unprecedented ways, in identifying and characterizing metabolites in both discovery and development environments.

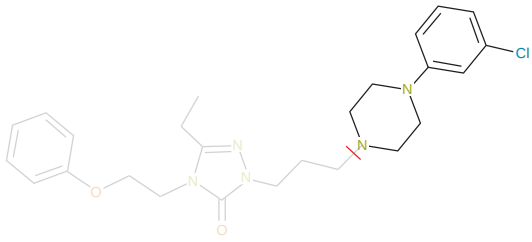
This application solution brings unparalleled ease and efficiency to routine Met ID processes.

As a consequence, scientists can rapidly derive results from complex data sets, and focus their time and skill on efforts that fuel and accelerate the discovery and development process.

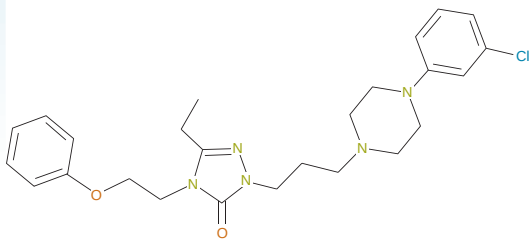
This allows scientists to communicate results to colleagues – and get those results to key decision-makers – faster.



ent name: Nefazodone+Hydroxylation
6.2269 Da
ed RT: 1.1961 min
rror: 0.5016 ppm

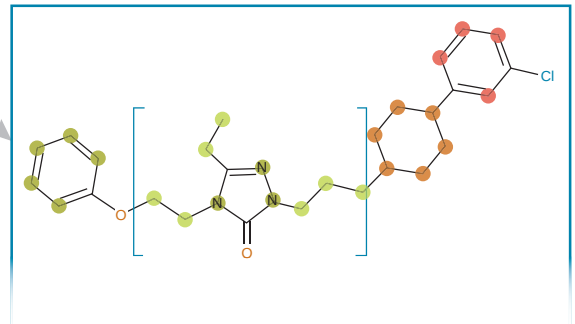


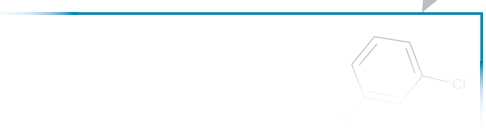
Component name: Nefazodone-C15H19N302 (dealkylation)
m/z: 197.0839 Da
Observed RT: 0.9242 min
Mass error: -0.289 ppm



Component name: Nefazodone
m/z: 470.2309 Da
Observed RT: 1.5902 min
Mass error: -1.768 ppm

< An information-rich, interactive metabolism map generated in UNIFI. As a key piece of the application solution, you will have the tools to confidently answer the question, "Should this compound go forward?"





Not just an evolution – a true revolution.

A total solution – built to excel in metabolite identification, and to incorporate quantitative tools that were developed specifically for other DMPK critical tasks in regulated bioanalysis – all in a compliant-ready software environment.

The Metabolite Identification Application Solution with UNIFI is more than a collection of interconnected instruments. It truly is a total solution – born of customer-driven insights and more than a decade of collaboration with industry experts. The unique benefits reside in a collection of hardware, software, methods, chemistries, standards, and reagents that are holistically designed to work optimally and establish an entirely new standard of what's possible in metabolite identification.

Integral to this application solution is UNIFI – the first and only Scientific Information System that keeps your scientists and your lab at the forefront of the most advanced technologies. UNIFI changes what you can accomplish with your analytical equipment.

It integrates and consolidates state-of-the-art data acquisition, data processing, and data management software capabilities – letting you solve specific analytical problems within a single platform.

WATERS ANALYTICAL STANDARDS AND REAGENTS

Precisely formulated calibrators, controls, and standards to ensure that your system is fit for purpose for metabolite ID, and for quality and consistency from day to day, system to system, and lab to lab.

ACQUITY UPLC I-CLASS SYSTEM WITH PDA

Faster sub-2-µm separations with excellent peak capacities for enhanced MS sensitivity, and advanced optical detection for high chromatographic sensitivity – perfect for complicated matrices such as plasma, bile, urine, and feces.

XEVO G2-S QTOF

Uses proven quantitative Tof (QuanTof™) technology and StepWave™ ion optics to deliver superior UPLC®-compatible mass resolution, matrix-tolerant dynamic range, quantitative performance, mass accuracy and speed of analysis – simultaneously.

UNIFI SCIENTIFIC INFORMATION SYSTEM

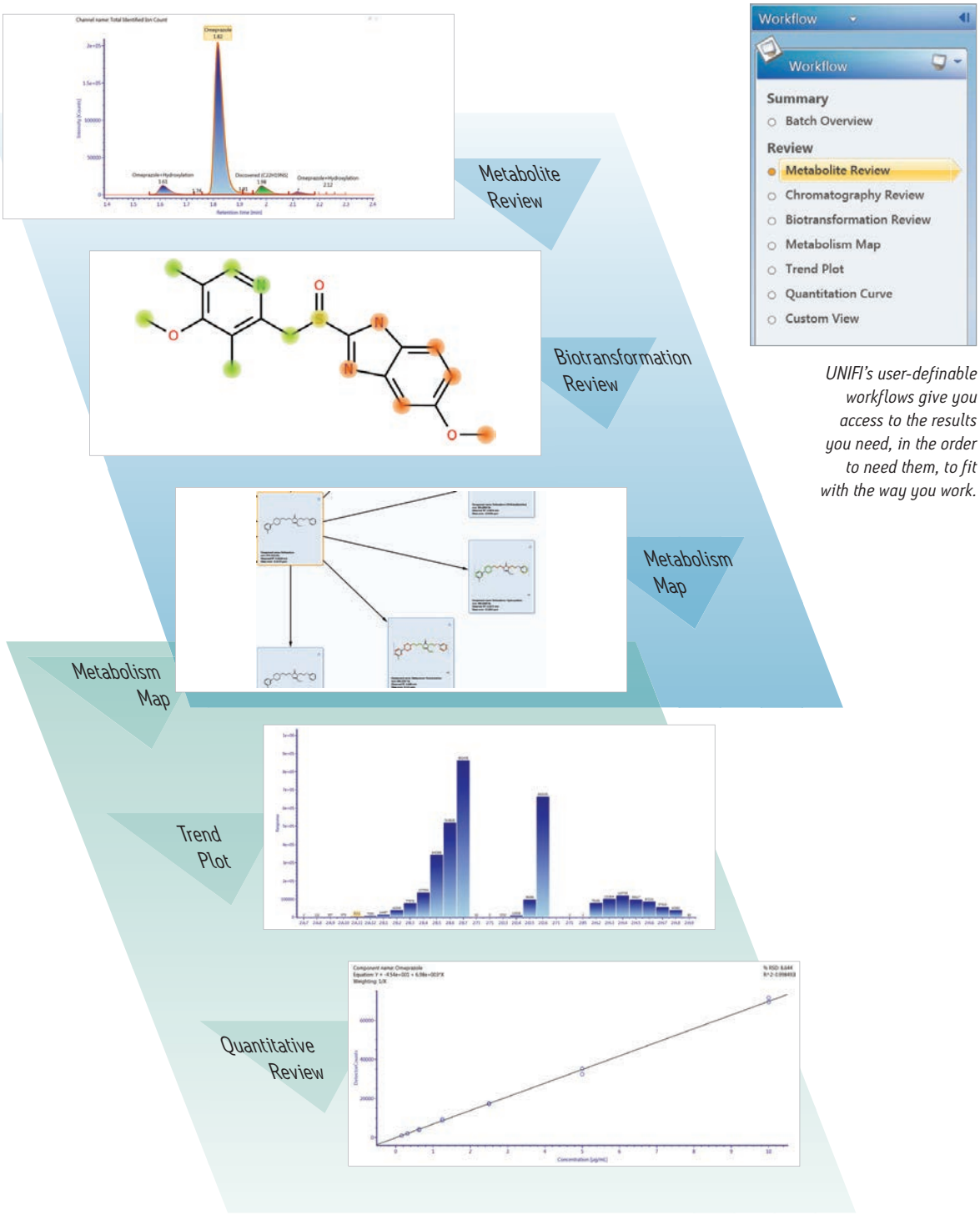
Built upon a scalable architecture to migrate from a single workstation to a collaborative enterprise deployment with ease. It easily stores, make use of, and allows sharing of all data, all methods, all reports – everything associated with analytical results across an organization. UNIFI uniquely enables leveraging today's information to share knowledge and solve for tomorrow's challenges.

Accelerate your science, redefine what's possible.

With this flexible solution, now you can get the answers you need for your drug metabolism studies wherever you are in the process.

UNIFI enables you to customize the workflow to your particular needs, so you can generate information and integrate the results into your current process.

The barriers between acquiring analytical knowledge and making information-driven decisions from discovery to market are now broken.



UNIFI's user-definable workflows give you access to the results you need, in the order to need them, to fit with the way you work.

PURE PROGRESS.

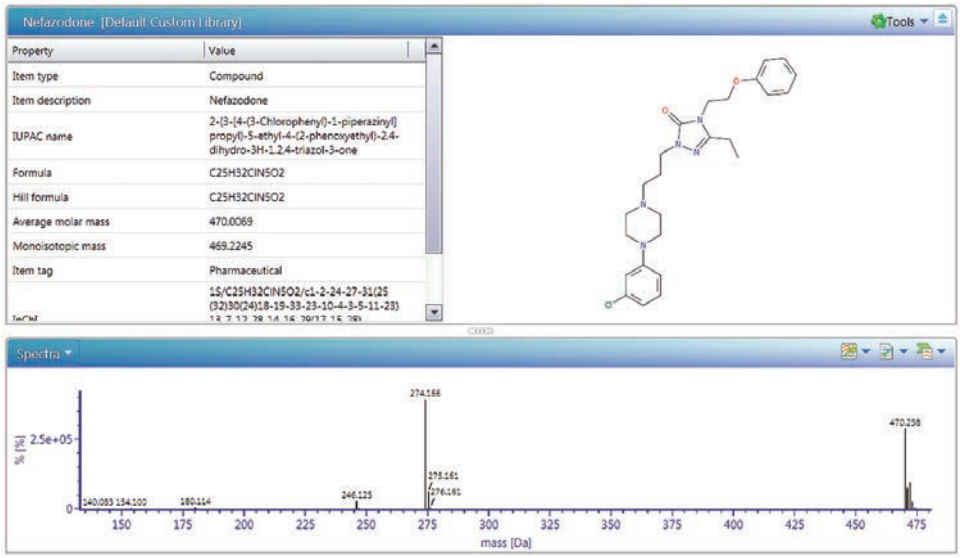
The UNIFI advantage.

UNIFI is designed to put a vast array of standard biotransformations at the scientists' fingertips, while predicting metabolic pathways based upon the structure of the molecule of interest. Allowing discovery and development scientists to be far more confident in the integrity and completeness of the results returned.

Should an unexpected metabolic event be discovered, UNIFI records the occurrence and stores that information in its scientific library.

This repository of information builds as each scientist uses and contributes to it – allowing the entire laboratory to work in the context of a growing body of information.

From regulated bioanalysis to metabolite ID, UNIFI enables every DMPK scientist to make better decisions based upon their own work and the work of their peers.



True information accessibility with UNIFI's scientific library. Example shown is nefazodone with gold-standard fragmentation spectra in UNIFI.

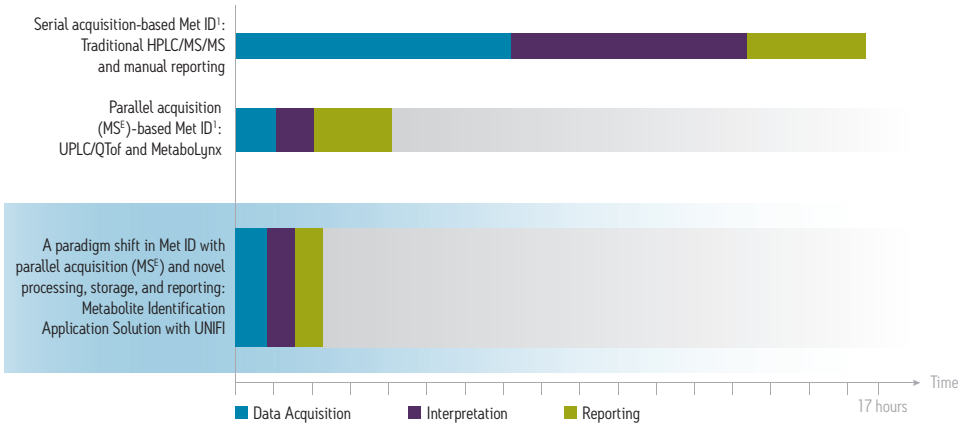
Dramatically enhance collaboration possibilities.

All over the world, DMPK scientists and labs are constantly striving to enhance collaborative drug discovery and development. Perfectly suited to meet these demands, Waters' next-generation application solution allows scientists to drastically compress the data acquisition, interpretation, and reporting timeline – to allow for more analytical capacity and collaboration.

This means that instead of spending extended periods of time conducting lengthy analyses, writing reports, and feeding information back to colleagues, scientists are able to quickly proliferate a high level of understanding throughout their organization. And can better use their time to focus on efforts that will advance their scientific goals.

"Before, I could spend as much time writing the report as I did running and interpreting the data. Now is the time for a sea change in quantitative DMPK studies."

PHILIP R. TILLER, Ph.D.
Vice President, RMI Laboratories



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Reference

1. High-throughput, accurate mass liquid chromatography/tandem mass spectrometry on a quadrupole time-of-flight system as a 'first-line' approach for metabolite identification studies. Tiller PR *et al.*, *Rapid Commun Mass Spectrom.* 2008 Apr;22(7):1053-61.

www.waters.com/metid

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