

A global call for good informatics practices



International survey of life science professionals reveals need for trusted IT guidance.
 By **Howard Asher**, Founder and Chairman of the LSIT Global Institute

There is no question that advancements in IT promise dramatic leaps forward in our ability to discover, develop and deliver new medical diagnostics and therapeutics. Utilizing these emerging information technologies, however, is not without its problematic issues. Among these problems plaguing the life sciences industry is how to cost-effectively implement these new technologies and validate IT systems to a long list of unknown benchmarks, ill-defined by global regulators. Without guidance, IT continues to be a black hole of investment and uncertainty for the industry.

In a recent international study conducted by the Life Sciences Information Technology (LSIT) Global Institute, 87 percent of senior life science professionals surveyed agreed that more consistency in IT practices among and between life and health sciences companies would significantly accelerate the regulatory approval process.

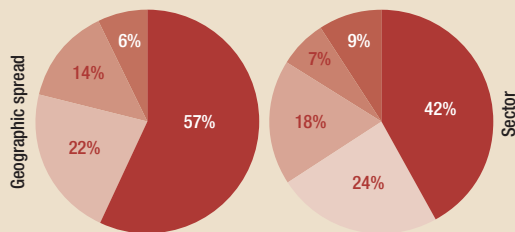
The survey sought the views of life and health science professionals worldwide who are engaged in IT – 33 percent of whom identified themselves as executive management level, 67 percent as director level and other IT professionals.

The LSIT Global Institute – a US non-profit, public benefit organization – conducted the survey as part of its efforts towards building trust of IT utilized within the life and health community. LSIT is an alliance of leading global life sciences and information technology companies, renowned aca-

demical and medical research institutions, healthcare providers, payers and representatives from government regulatory agencies worldwide.

LSIT will use this study to map out and prioritize the development of Good Informatics Practices (GIP) guidelines that can be adopted by global industry and regulators. We envision that GIP will provide significant benefits, as have other critically important good practices in place today, such as GLP, GMP and GCP. This prediction is supported by the survey results,

Other key demographics of respondents:



Geographic spread: Americas 57%, EMEA 22%, APAC 14%, Other 6%
 Sector: LS 42%, IT 24%, R&D 18%, HC 7%, Other 9%

Survey Access: BioIT World & LSIT Global Institute

Identifying the problem

"We could significantly improve our organization's IT standards and practices"

5.5% 10.2% 82.7%

Disagree Agree

Stongly Somewhat Neither Somewhat Strongly

"More consistency in IT practices among and between life and health sciences companies would significantly accelerate the regulatory approval process"

3.1% 7.1% 86.6%

Disagree Agree

Stongly Somewhat Neither Somewhat Strongly

IT knowledge/leadership

"There is clearly a need for a centralized knowledge base or repository for IT best practices for the life and health sciences community."

4.7% 7.1% 87.4%

Disagree Agree

Stongly Somewhat Neither Somewhat Strongly

"There is clearly a need for an organization to take the lead in helping the life and health sciences community develop its own set of IT best practices."

5.5% 15.7% 77.2%

Disagree Agree

Stongly Somewhat Neither Somewhat Strongly

Good practices

"Good Informatics Practices (GIP) would significantly improve our business processes and improve our regulatory compliance."

3.9% 17.3% 76.4%

Disagree Agree

Stongly Somewhat Neither Somewhat Strongly

which suggest that an opportunity exists for GIP to level the IT global playing field much in the same way that the International Conference on Harmonization (ICH) did by establishing GCP guidelines in the conduct of regulated clinical research.

Highlights of the 31 question survey are shown opposite.

Asked to select the primary reasons each organization would adopt GIP (checking all that apply), 60.6 percent of respondents cited the simplification of integration of other IT standards and practices, while 55.9 percent chose reduced costs and time of IT validation. A reduction in costs of new IT implementation and reduced IT risk were selected by 52.8 percent each, while 44.9 percent of respondents found reduction in time-to-market to be a prime driver for adopting GIP.

LSIT is currently under way with the development of GIP guidelines. This collaborative process will be accomplished by weaving appropriate international IT standards in with IT best practices, and applying detailed consideration to the special needs of the life and health sciences community.

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As trust in IT systems utilized in the life and health sciences expands, it will permit more rapid and exacting discovery and development of medical therapeutics and diagnostics with savings in time and cost from discovery to the patient. The survey asked: "Assuming your organization could be provided with clearly documented, globally-accepted (including regulatory agencies) GIP guidance, how likely would your organization be to adopt GIP specific to the following areas?"

The IT industry has a great opportunity to apply its core competence with assisting in the development of GIP and offering products and professional services that are 'GIP certified'. The life and health sciences community therefore needs the IT vendors and professional service providers to warmly embrace the special needs of this community.

GIP guidelines will enable trusted computational tools that will effectively approach more elusive diseases, such as tuberculosis, diphtheria, HIV and perhaps even the common cold, at the cellular level. Trusted GIP guidelines will enable IT tools such as computational predictive modeling and personalized medicine to become a reality. Trusted IT systems will also afford IT-enabled personalized diagnostic medical assessments of patients, which will permit matching the right medication to each patient's exact disorder, based upon their genotype or biomarkers. Enabling 'trust' in the IT systems utilized in the life and health sciences will allow much more advance efforts to rapidly improve global public health. ■

The 31-question survey was conducted via the internet from April through June, 2005 with special assistance provided by BioIT World. For more information about the LSIT Global Institute and results from this study, please visit www.lsit.org.