

Dateline: 18 December 2015

In 14 days, a promising cure for prostate cancer (X.21) readies for Phase III/IV corroborating clinical studies...

Two weeks ago, scientists announced they had discovered a potentially potent, small molecule, X.21, believed to be a breakthrough in the fight against prostate cancer. They challenged their discovery against the global prostate cancer patient database and performed extensive Insilco safety and efficacy with computational predictive modeling (CPM). The findings were conclusive – the X.21 was run against 346,000 actual prostate cancer patients who have contributed their health informatics to the global prostate cancer patient database that enabled the CPM for this disease.

According to Dr. Clarence Seymour, Director of the National Cancer Institute: "This is the third demonstration in the value of CPM and rapidly bringing safe and effective therapeutics to cancer patients. The previous two experiences clearly demonstrate that we can, at last, trust this advanced information technology to deliver on the promise."

Seymour further indicated: "We can now see at the cellular level the exact effects these potential therapeutic molecules have on cancer patients before any actual human testing. As with the previous two therapeutics utilizing the CPM, we saw in the Phase III/IV corroborating clinical studies exactly what the CPM demonstrated – absolutely no surprises. This permitted these two therapeutics to go from discovery to the cancer patients, worldwide, in less than five years. Even more exciting, by this dramatic reduction in time and research investment, we are seeing these novel drugs being released at a small fraction of the price of previous drugs developed, within the old paradigm."

If we could just trust IT, what a healthy world it would be.....

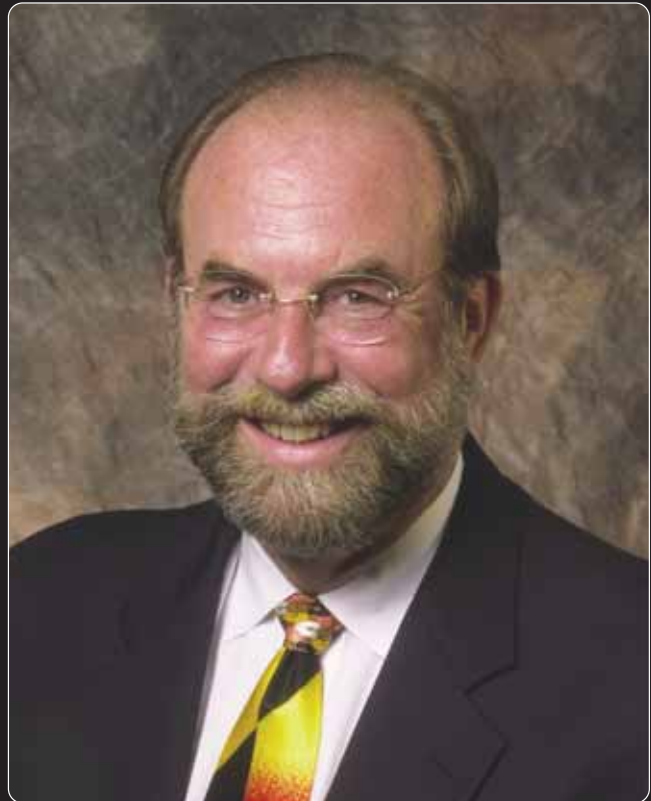
By Howard Asher, Founder and Chairman of the LSIT Global Institute

The Life Sciences-Information Technology (LSIT) Global Institute is determined to make this fictitious scenario a reality.

The life and health sciences community are 'late adopters' of IT, especially when compared to the financial, transportation, telecommunications, energy, entertainment and many other communities. The IT industry has had a difficult time relating to the specific needs of the life and health sciences community. For example, IT industry analysts have for years referred to the life sciences industry (e.g. Pfizer, Lilly, J&J, etc.) as 'discrete manufacturers' and lumped their IT spend in with the likes of manufacturers of specialty products (i.e. auto parts and washing machine makers, etc.). This draws little distinction to the very special IT needs of this highly regulated life sciences industrial sector.

When the IT industry first started learning of this life sciences industry they assumed that US FDA's Code of Federal Regulations, Title 21, Part 11, for example, was nothing more complicated than Y2K. And they treated it as such – with terabytes of misinformation. As they focused on healthcare providers, they learned of the US Department of Health and Human Services federal law protecting patient's privacy, HIPAA, and petabytes of misinformation were disseminated. The IT industry also broke down this life and health sciences community into their own bite-sized pieces. The medical research sector was 'education', the life sciences industry was 'discreet manufacturers', and the healthcare providers were 'healthcare'. Thus far, only one IT company, IBM, has finally got it right. The company has consolidated its approach to this life and health sciences community as – a community.

For over two centuries we have approached health the same way. We have always gone from the needs of public health, to medical research and discovery, to development and to the patient – as one contiguous community. It is codependent, it must be, and it cannot be separated, especially with its information. It does not matter if the information is managed



Howard Asher founded the LSIT Global Institute while Group Director of Global Life Sciences at Sun Microsystems. Highlights in a lengthy and esteemed career have included 20 years as President, CEO and Chairman of Advanced Bioresearch Associates (ABA), a company he founded himself back in 1979. ABA, which grew to be the principal FDA regulatory affairs consulting firm for life science company clients worldwide, focused on making business sense of developing medicinal products in a heavily regulated environment.

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by technology or not, it must commingle. What happens to a patient in a hospital has great importance to medical researchers and to life science industrial companies that develop medical diagnostics and therapies. It is all about public health, global public health. When HIV was first diagnosed in New York city, we knew we had a serious global health concern.

Many years ago, the IT industry began taking an interest in the banking community. It was fascinated by the rapidly growing daily transactions. To the IT industry, this meant data – vast amounts of critical data. As the IT industry got closer to the banking industry, it began to learn of its special needs. For example, time of information processing was of the essence. Trust and privacy of the transaction, perhaps even more important. To cut a very long story short, the automated teller machine was born. It was globally considered and globally developed and, most importantly, the public had to trust it.

“Trusting that these very complex IT tools, computational processes and resulting data are in fact accurate and valid is critical for all stakeholders and gatekeepers alike”



About the LSIT Global Institute

The Life Sciences-Information Technology (LSIT) Global Institute is a not-for-profit organization chartered with the sole purpose of developing open source IT architectural references as a basis for good informatics practices for the life and health sciences community. The effective and appropriate use of IT offers the promise of reducing time to market and accelerating new medical therapeutics and products from discovery to the patient. The organization's members are an alliance of leading global life sciences and information technology companies, renowned academic and medical research, institutions, healthcare providers, payors and representatives from government regulatory agencies worldwide.

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The public must also trust the IT convergence into the life and health sciences community. IT is not among the top 10 core competencies of the medical research sector, the life sciences industrial sector, nor the healthcare

provider sector. Nor is it a core competency of the US FDA or the other 49 industrialized nations that regulate the life and health sciences community, in protection of its public health. Nor should it be.

Like the case with the banking community, the life and health sciences community must come to depend on the IT industry's number one competency – IT. But, like it did in the banking community, the IT industry must invest in carefully learning the special needs we have. Once they do, we too could have something as powerful and revolutionary as the ATM.

We could have the CPM...

The integration of information technology into the life and health sciences is rapid and profound. This integration has real potential for reducing both the time and cost of bringing new medical therapeutics and products from discovery to the patient. The one main inhibiting factor is 'trust'. Trusting that these very complex IT tools, computational processes and resulting data are in fact accurate and valid is critical for all stakeholders and gatekeepers alike. ■



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Given the high intellectual capital and extremely positive investment climate, the Czech Republic has become the favorite location for foreign direct investment in Central and Eastern Europe. Global life sciences companies (Lonza, Baxter, Ivax, Pliva) have set up their state-of-the-art facilities in the country. Many others (AstraZeneca, GlaxoSmithKline, Novartis, Aventis, Janssen-Cilag, etc.) have recognized the advantages of the Czech Republic and started their business activities - many of them even conduct CRO and clinical trials. Several others are now negotiating their investment plans at CzechInvest.

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