



**A conversation with the Conference Chair
Craig Lipset, Pfizer**



Craig Lipset is Director and Commercial Lead for Molecular Medicine at Pfizer, working from the company's New York corporate headquarters.

At Pfizer, Craig is responsible for several technology-based innovative initiatives spanning clinical and commercial. Prior to Pfizer, Craig served as Associate Vice President of Program Management at Adnexus Therapeutics

(acquired by Bristol-Myers Squibb), and was a founding employee with various leadership positions at Perceptive Informatics (later operating as a subsidiary of Parexel International).

He serves on the editorial board of the Drug Information Journal, and as an advisor to a patient research and advocacy organization.

Tell us a little bit about your self and your passion points.

Craig: Thank you. My career has span from investigator sites, coordinating centers, CROs, technology companies, and biopharmaceutical sponsors. I've had the opportunity to work at startups and multinational corporations. Each of these stakeholders has an important contributing role to play in setting the future of clinical research. This is where my passion comes into play. The sustainability of clinical development as we know it today is in jeopardy. My work and passion are around ensuring that we're able to sustain our collective ability to deliver new medicines to patients in need. We work in a phenomenal industry. Our products extend life, they improve human health, but our industry is struggling like never before. The metrics are well known drug development cycles are long and costly, success rates such as the percentage of drugs reaching approval remain low, and investment in R&D dollars has increased, while the number of new medicine reaching the market has fallen by about half

over the last two decades. There is an urgent need for innovation to improve our R&D productivity and this is where my passion lies.

You are the esteemed Conference chairperson for 2010 and have been part of the event for at least 6 years now as a presenter and an advisory board member, why does this conference resonate with you?

Craig: This conference really speaks to an exciting crossroad. It's at the intersection of novel science applied to the drug development process. It addresses our ability to leverage an innovative tool kit. This kit includes, but is not limited to, laboratory sciences, cardiac monitoring, and imaging. This kit spans the entire drug development continuum, from improving decision making in early development to accelerating our ability to demonstrate efficacy and safety in the context of late phases development, and even enable our ability to deliver personalized therapies to patients in the clinic. Some instances, we're talking about tools where the science is still emerging, and elsewhere, the science can be mature. Each of these areas has their own unique business challenges. This conference brings together the science and business, enabling us to change the business challenges into opportunities and solutions. This year's keynote speaker exemplifies this crossroad like no other. James Watson and his colleagues uncovered the structure of DNA and received a Nobel Prize in Medicine back in 1962. In many ways, we're just on the cusp of understanding how to fully leverage this knowledge and convert it into medicines to improve human health.

Can you discuss how industry continues to explore novel imaging techniques in the context of their early phase development programs?

Craig: As I mentioned earlier, success rates of clinical trials remains low and our spend has steadily increased. We need better and smarter ways to make effective decisions ensure we're moving the right compounds forward, and doing that in a timely manner. In many therapeutic areas, novel imaging techniques are giving us the data we need to make those decisions. We have see this in the oncology, but the impact spans many therapeutic areas. And as the science of medical images advances in its own lifecycles -- in academia and in the clinic -- so do the applications to leverage medical imaging, to answer the questions regarding the efficacy and safety of the medicines we're developing.

Can you tell us about some of the standardization taking place in the industry?

Craig: The use of effective standardization techniques has really been one of the central points for the successful use of imaging in drug development for many years. Methods for image acquisition can vary across scanners, across sites, and across countries. So we have a long history of investing in efforts to standardize image acquisition within a given protocol. We use prescribed sets of imaging guidelines, we use training procedures, quality control checks and a number of

other necessary interventions. We are now seeing efforts around standardization moving to a new level. Sponsors, labs and academic groups are coming together in an attempt to share image acquisition protocols and where its appropriate, work to narrow the gap between clinical trial imaging and the imaging in clinical practice. Ultimately that will further improve quality.

We also see sponsors and labs coming together to standardize performance metrics. Groups working with like the Metrics Champion Consortium -- in a process that has already shown success for central labs, EKG Labs, and CROs -- now the imaging community has come together and developed a set of standardized metrics of their own. They're now being leveraged in the context of continuous improvement and quality benchmarking.

What do you see coming in the future for this industry?

Craig: I guess there are a few areas that could come together in the future. The field of imaging and clinical trials has recently seen a resurgence in the use of the web as compared with couriers for transferring images from sites to central labs and image repositories. Using the internet for web-based image transfer enables faster data quality control at a fraction of the price. We should expect to see further uptake in that approach.

In parallel, sponsor companies have continued to explore the value of their own imaging data, building a range of solutions for centrally archiving their images for future mining. These digital image warehouses can then function in a similar way that we have seen the industry use biobanks in the past.

Some forecast the future of drug development with rolling submissions for new medicines. A group of medicines may be available faster to a small subpopulation and may then expand to broader populations as additional data is collected over time. In this type of model, imaging can play an interesting roll in both the early demonstration of efficacy in subpopulations as well as the ability to monitor response to that therapy in larger populations in support of more broad approval.

Beyond imaging, each of the labs domains addressed at the Central Labs conference is based in a clinical science. So their future will also be dynamic and interesting. And this goes back to the spirit of functioning at the crossroad between breakthrough laboratory sciences and clinical trial processes. New and exciting methods will continue to be explored by academia and others. With each new technique will come new opportunities to answer questions that are critical to our understanding of drug mechanisms, safety, and efficacy and so on. I think it's that constant flow of innovation that will continue to make the topic of central labs interesting into the future, and ensure that this Central Labs conference remains relevant.