13TH ANNUAL BIOMARKERS CONGRESS

Pre-Event Newsletter

MANCHESTER CENTRAL CONVENTION COMPLEX

15 - 16 FEBRUARY 2018 | MANCHESTER, UK

OXFORD GLOBAL

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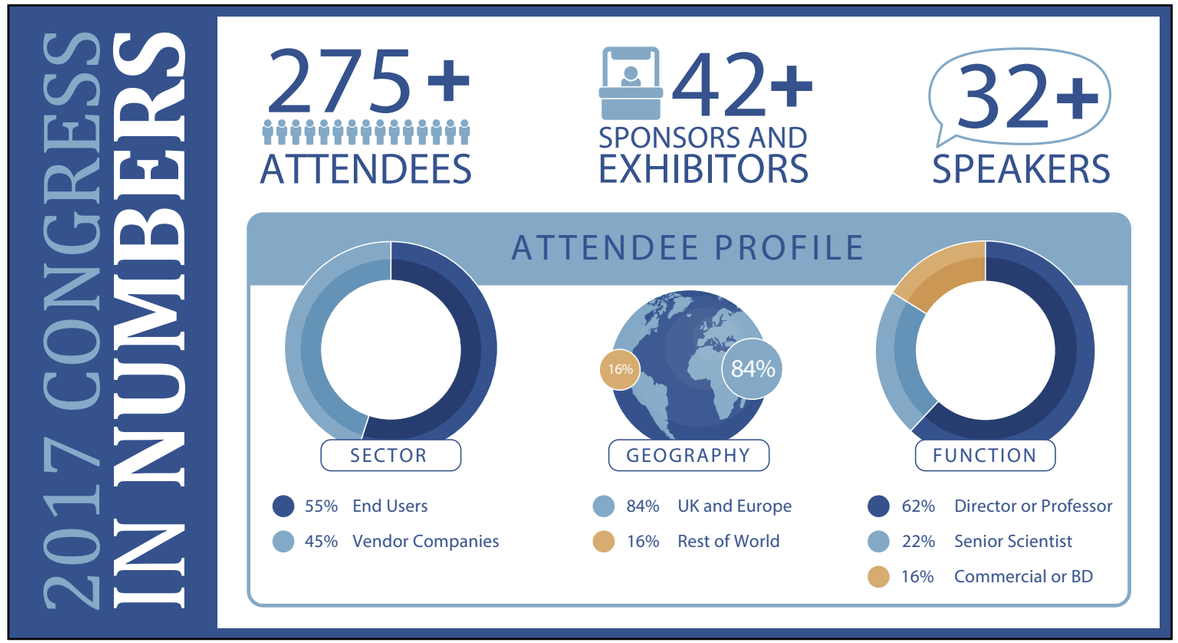

WELCOME TO THE 1ST EDITION OF OXFORD GLOBAL'S ANNUAL BIOMARKERS UK CONGRESS NEWSLETTER!

With the 13th Biomarkers Congress taking place in February 2018 in Manchester, I am delighted to look back at some of the highlights of the 2017 event and provide some details on a few of the key features & exciting additions for the 2018 congress.

The 2017 congress brought together over 250 attendees in Manchester to discover collaborative solutions to biomarker discovery & development challenges and discuss the latest developments in innovative biology & genomic markers. Alongside the exciting talks and extensive networking opportunities, 2017 saw the welcome return of our congress dinner, with the post event feedback proving that food and beverages really are the way to people's hearts!

The 2018 event will feature 60+ presentations on key topics within **Biomarkers In Drug Discovery & Development, Personalised Medicine, Precision Medicine & Companion Diagnostics, Innovations In Biomarker Research** and **Biomarkers In Clinical Development & Clinical Trials** from industry leaders. Alongside this, we're pleased to introduce a comprehensive workshop looking at **Scientific And Regulatory Considerations For The Analytical Validation Of Assays For The Qualification Of Biomarkers** AND a chance to hear and discuss perspectives on challenges, advancements & ongoing work within the Biomarkers industry in the dedicated **Think Tank Round Table Discussions & Breakfast**. The 13th Biomarkers Congress will also see the launch of our **Biomarkers Directors Club**, offering leaders within the pharma & biotech sector a host of exclusive benefits pre-event, onsite and post-event.

After a full day of learning, knowledge sharing and meeting new people, what better way to unwind after the first day of the congress than with a three-course sit down meal and a glass of wine (or two) at Albert Square Chop House in Thomas Worthington's iconic Memorial Hall. The evening promises good food, good wine and great company!

Read on for a range of interesting interviews and insights with some of 2018's industry-leading speakers and participating sponsors, and I look forward to welcoming you to the 2018 Congress in February ■

13TH ANNUAL BIOMARKERS CONGRESS

MANCHESTER CENTRAL CONVENTION COMPLEX | 15 - 16 FEBRUARY 2018

WHO IS ATTENDING?

For the full attendee list please contact
marketing@oxfordglobal.co.uk

- **300+ senior level attendees** from leading pharmaceutical, biopharmaceutical, biotechnology, diagnostics, CRO and solution provider companies.
- **Highly esteemed members** of academic and government institutions.
- **VPs, Directors and Global Heads** of biomarker identification & development, translational medicine, precision medicine, companion diganostics and biomarker safety.

These companies and many more:

abbvie · AstraZeneca · AMGEN · janssen · Celgene · ucb · Roche · BAYER · Astrimmune · Genentech (A Member of the Roche Group) · NOVARTIS · Boehringer Ingelheim · Bristol-Myers Squibb · SANOFI GENZYME · MedImmune

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IN CONVERSATION WITH DR. BOB HOLT

BerGenBio

Bob has over 15 years' experience in the biomarker and companion diagnostic industry working for both diagnostic and pharmaceutical companies. Bob joined BerGenBio in 2017 and is responsible for all aspects of biomarker discovery and companion diagnostic development across the BerGenBio clinical pipeline.

Prior to moving to BerGenBio Bob spent over 10 years working in biomarker and diagnostic contract research at both Almac and Hologic providing biomarker discovery and companion diagnostic development services to pharmaceutical companies.

Bob has considerable experience of diagnostic product development, from early biomarker discovery through to the development of commercially available, approved diagnostic products. Bob has an undergraduate degree from the University of Dundee and a PhD from the University of Liverpool. Additionally, he has authored several key biomarker publications in peer-reviewed journals, book chapters and is an inventor on a number of biomarker patents.

Dr. Bob Holt, Director of Biomarkers & Companion Diagnostics at BerGenBio ASA, shares his thoughts with us on the use of biomarker technologies in the future of healthcare, CDx, and personalised medicine programs.

What are your views on the role that biomarkers will play in the future of healthcare?

Biomarkers have played a key role in healthcare for centuries, even simple things we take for granted like having your temperature and blood pressure taken are in fact biomarker based tests. In recent years our understanding of disease biology, the mechanism of action of drugs and our access to immensely powerful technologies such as next generation sequencing has fundamentally altered medical practice. The use of companion diagnostic (CDx) tests now allows treatment decisions to be made based on the results of complex biomarker tests allowing patients to receive a treatment that is right for them.

The use of companion diagnostic (CDx) tests now allows treatment decisions to be made based on the results of complex biomarker tests allowing patients to receive a treatment that is right for them.

How important is biomarker discovery in the development of a companion diagnostic test?

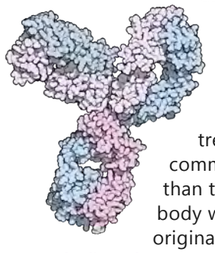
The discovery and validation of a predictive biomarker is a pivotal step in the development of any companion diagnostic - without a biomarker there is no test. In addition there are two major stakeholders in the CDx development process with very different roles to play; the pharmaceutical company developing the drug and the diagnostic company developing the biomarker based test.

Biomarker discovery is a key activity for the pharmaceutical company particularly during preclinical and early stage clinical studies. At this stage it's critical for the pharma company to keep one eye on the future of the biomarker and ask, "what will this look like in the clinic"? This is particularly important when it comes to platform and chemistry choice, for example if there is a choice between two candidate biomarkers, one of which is a new technology that only works on a fresh frozen biopsy and another which is based on a standard blood based assay the sensible decision would be to choose the blood based biomarker to develop into a CDx.

To take a biomarker and turn it into a regulatory approved, commercially available diagnostic product requires capabilities that the majority of pharma companies don't have so it will be necessary to partner with a diagnostic company. From the diagnostic company's standpoint biomarker discovery forms a very small part of the product development process. Key activities for the diagnostic company in the development of a CDx include regulatory interactions, design control, manufacturing and reimbursement all of which will require continuous input from the pharma company throughout the product development process.

In your opinion what have been the most important developments in personalised medicine over the last 12 months?

For me the standout development of last year was the U.S. Food and Drug Administration's approval for treatment of cancers with a specific biomarker using pembrolizumab regardless of disease indication. This is the first time the agency has approved a cancer treatment based on a common biomarker rather than the location in the body where the tumour originated and represents a paradigm shift in the way cancer can now be treated. Historically drugs were approved for specific disease indications, e.g. breast cancer, this latest approval allows patients with any cancer with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) to be treated with pembrolizumab.



pembrolizumab (artist's impression)

What are the biggest challenges in integrating a personalised medicine program into a drug development pipeline?

Without a doubt the biggest challenge is the timelines involved, it's critical to identify a predictive biomarker as early as possible in the drug development process, ideally during pre-clinical studies. The nature of Phase I and Phase II trials means they are often of limited use when it comes to biomarker discovery primarily due to sample numbers and the availability of tissue samples. The next hurdle is the transition from Phase II to Phase III studies, at this time a locked down predictive biomarker is required together with a suitable Phase III trial design and a diagnostic partnership in place. This represents an almost insurmountable hurdle, something which has now been recognised by regulatory authorities who acknowledge the need for retrospective biomarker/CDx studies ■

Hear more from Dr. Bob Holt at the 13th Annual Biomarkers Congress

On day one, at the panel discussion **'Precision Medicine & Integrating Diagnostic Testing In Drug Development For Patients'**

On day two, at his think tank roundtable discussion: '**Biomarkers And Companion Diagnostics Development'**

END-TO-END DRUG & DIAGNOSTIC DEVELOPMENT SUPPORT FOR A NEW IMMUNO-ONCOLOGY AGENT: A CASE STUDY

Immuno-oncology drug development is inherently complex and requires special considerations across the entire spectrum, from preclinical to commercial support for the approved product. In this example, a prominent pharmaceutical company was developing an innovative new programmed death receptor-1 (PD-1)-blocking antibody indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC). This company selected Covance / LabCorp for support at multiple junctures—from manufacturing to biomarker evaluation to market access—to enable a faster and more effective launch.

Key Highlights of This Case Study:

- Speed to market was crucial—rival companies were pursuing the same or similar indications with therapies having a similar mechanism of action, creating deadline pressure without compromising trial success.
- The molecule required the co-development of a diagnostic laboratory assay, which requires a distinct set of capabilities and CRO / diagnostic company collaboration.

The Common Denominator

Multiple functions touch the drug development path. At Covance, our relationship with LabCorp gives us a unique capability to perform end-to-end services to support trials, starting as early as nonclinical work. In this case, our diverse early development services group—including BioPharm CMC—was engaged to assist in the manufacture and qualification of drug lots that went out to trial use.

Moving from Early Development to Central Laboratory services, Covance provided biomarker evaluation to enroll patients in pivotal clinical trials, enabling patient stratification and selection for trial participation which were critical to the therapies' approval. In addition work was done with an *in vitro* diagnostic company in the co-development of the diagnostic laboratory assay, so that it could be available at the same time as the therapy. This was facilitated through the extensive experience LabCorp has in supporting such test development and then commercially launching the test to coincide with the drug's launch.

The immunotherapeutic launched with great success for patients, but still encountered some market access challenges. Its proposed buy-and-bill model—along with high product costs—required careful understanding and communication about payer policy and coding. Covance Market Access was selected to provide post-launch commercial support—specifically a robust reimbursement strategy to: 1) fend off a rival's encroachment with a similar oncology product; 2) handle access-related issues unique to each oncology provider to facilitate more efficient reimbursement and build stronger provider relationships; and 3) improve overall market access in an increasingly competitive space.

Covance's reimbursement team educated healthcare providers on the client's access services so that they could easily obtain billing and coding support, co-pay assistance and handle underpaid or denied claims. By providing crucial insights, maintaining provider relationships and quickly responding to case-specific concerns, Covance was recognized as an integral part of the client's oncology field team that helped strengthen market presence.

Lastly, for post-approval, Covance CMC in Harrogate (UK) was retained for release and stability testing to verify quality of the manufactured product for its intended audience.

Value to the Client

Most of the FDA-approved diagnostics used to guide therapy decisions are primarily for oncology indications. In addition, most oncology drug development initiatives are biomarker-driven. With so many of these new therapeutics earning a Breakthrough Designation and/or fast-track approval, there can be a significant benefit to having a single partner efficiently support multiple steps in the drug development and diagnostic co-development process. This consolidation of service outsourcing could result in a higher probability of success and accelerated speed to market.

In immuno-oncology, a variety of biomarkers and corresponding assays are being considered to help assess the efficacy of a therapeutic approach, and these include a variety of proteomic and genomic approaches that require specific expertise. As this vibrant area of research continues to expand the options for oncology treatments, Covance's combination of highly specialized expertise and comprehensive end-to-end drug development enables sponsors to better inform patient decision-making and advance the field of personalized medicine.

Covance and LabCorp have supported more than 75% of all FDA-approved diagnostic assays included in drug labels, involving both companion and complementary designations.

Learn more about our drug development solutions at **www.covance.com**

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CYTOMETRY-BASED BIOMARKER DISCOVERY AND DISEASE MONITORING IN IMMUNO-ONCOLOGY

PROFESSOR A. GRAHAM POCKLEY

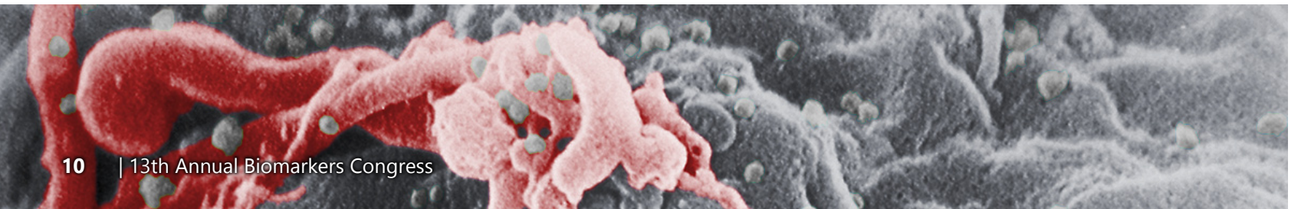
CEO at multimmune GmbH, Munich, Germany and Director at John van Geest Cancer Research Centre, Nottingham Trent University

Cytometry can be defined as the identification of cells and the measurement of cellular characteristics such as size, count and biological status. Although several platforms and devices can be used to measure such characteristics, flow cytometry and derivatives thereof are the most predominantly used approaches today. Flow cytometry is an optical, laser-based technology which interrogates the physical and fluorescent properties of cells in suspension in real-time as they flow through the instrument. Flow and imaging cytometry (which captures fluorescent images of cells that are being analysed) have a number of advantages over other techniques that can be used for characterising cell populations in single cell suspensions, in that they can non-subjectively interrogate millions of cells and acquire data on the presence of different cell sub-populations and phenotypical changes within these populations within seconds. Flow and imaging cytometry provide much higher-level information relating to the presence, phenotype and function of tissue-derived (isolated) and circulating tumour cells, and the major and minor lymphocyte subtypes (B cells, T cells, T cell subsets, natural killer (NK) cells etc) which cannot be achieved using other approaches.

Although progress in the diagnosis of cancer and in the development of new cancer therapeutics for the majority of tumour entities progresses at a pace, key challenges in the identification, management and treatment of aggressive disease remain, with 90% of cancer-related deaths being attributed to metastatic disease. It is therefore essential that biomarkers which reflect the presence of disease and its 'aggressiveness', and which can inform and direct therapeutic strategies are developed. One such biomarker is a membrane form of the 70 kDa heat shock (stress) protein which was shown to be selectively expressed on cancer cells by Professor Gabriele Multhoff using a unique monoclonal antibody (cmHsp70.1). Subsequent and ongoing studies which have used flow cytometry to analyse the expression of membrane Hsp70 by cancer cell lines and viable cells isolated from different tumours have revealed that this unique form of Hsp70 is expressed on 50-75% of all tumour entities, and that it is more highly expressed on metastatic and aggressive disease. The value of such analyses is that new therapeutic approaches that can specifically target tumours expressing membrane Hsp70 are being developed. These are based on *ex vivo* activated NK cells (currently undergoing Phase II clinical trial in patients with non small cell lung carcinoma), a recombinant form of the serine protease granzyme B (pre-clinical stage) and the cmHsp70 monoclonal antibody (pre-clinical stage) (see www.multimmune.com for more details).

Another novel application for cytometry in oncology is to exploit the reciprocal relationship between the tumour and the immune system, and use changes in the phenotype of peripheral blood immune cells ('immunome') as a 'biomarker' for the presence of disease. Although statistical analysis of immune phenotyping datasets relating to the presence and prevalence of key leukocyte populations (T cell subsets, B cells, NK cells, monocytes) in the peripheral blood, as generated from asymptomatic men with Prostate Specific Antigen (PSA) levels <20 ng ml^{-1} undergoing routine tests for prostate cancer (including tissue biopsy) using multi-parametric flow cytometry, was unable to identify significant relationships between the peripheral blood immunome and the presence of benign disease (no prostate cancer) or prostate cancer, advanced computational data extraction and prediction modelling of these data is able to (Cosma G et al, *Frontiers in Immunology* 2017, https://doi.org/10.3389/fimmu.2017.01771). Furthermore, combining flow cytometry-derived predictors with PSA levels improves diagnostic accuracy. Ongoing studies are using similar computational analysis and modelling approaches to interrogate and evaluate the diagnostic power of more deeply phenotyping individual cell subsets (Hood S et al, manuscript in preparation).

It is therefore apparent that multi-parametric cytometry can provide significant insights into the presence and nature of disease, and inform therapeutic decision-making (so called 'precision' medicine) in oncology ■



Q&A SESSION WITH MATTIAS BERGQVIST

VP Clinical Development at Biovica International

Mattias Bergqvist is Vice President Clinical Development at Biovica and has over 20 years of experience from the pharmaceutical and biotechnology industry. He has global responsibility for clinical development programs focused on providing proliferation markers in the evaluation of novel oncology drugs. Mattias has authored a number of publications in peer-review journals and studies presented at global scientific conferences.

What key things can a biomarker contribute with during preclinical and clinical drug development?

A biomarker should ideally be able to:

- provide key information across the development continuum
- give dose-response information and early signals of efficacy in vitro
- provide mode of action evidence of target efficacy
- bridge between cell cultures and studies in human
- complement other methods and markers adding valuable data to tollgate decisions
- predict outcome and give early indication of response/ progression in target population
- increase approval probability and speed to market, reduce attrition and cost.

How can proliferation biomarkers add value when evaluating oncology drugs?

Tumors are characterized by uncontrolled cell growth. Biomarkers that measure cell proliferation can be used to measure cell growth rate and provide early information of dose-response, in vitro efficacy, assist in tumor type selection, predict outcome and monitor efficacy. Analyzing the present growth rate can predict future response and time to progression instead of looking at volume change that reflects what has already happened. Ki-67 has been used for a long time to measure cell proliferation but requires a biopsy. Ideally, a proliferation biomarker can be used in cells and blood, providing a bridge between preclinical and clinical studies. Thymidine kinase (TK) activity is such a biomarker.

"In the era of immuno-oncology and targeted therapy new markers are needed to provide information on surrogate endpoints, cell growth inhibiting potential and apoptosis."

Are there specific oncology drugs that can be targeted with proliferation biomarkers?

There are many novel drugs within oncology aiming to slow down or shut down cell growth. Many different signaling pathways are targeted that inhibit the cell cycle and shut down uncontrolled cell proliferation. Serum TK activity have demonstrated to be a strong pharmacodynamic marker for new, targeted drugs like CDK4/6 inhibitors and an early efficacy marker for evaluating endocrine therapy. In the era of immuno-oncology and targeted therapy new markers are needed to provide information on surrogate endpoints, cell growth inhibiting potential and apoptosis.

New results with a serum proliferation biomarker, the DiviTum TK activity assay, has recently been presented in breast cancer. What did the new data reveal?

In a study of 142 women with metastatic breast cancer (presented at the 2017 San Antonio Breast Cancer Symposium, P3-08-13) it was demonstrated that DiviTum is an easy, fast and flexible method that predicts progression free- and overall survival. At all measured time points; diagnosis and after 1, 3 and 6 months of therapy, DiviTum accurately predicted outcome. This dramatic shortening of the evaluation window, already after one month of therapy, can be key when making decisions to continue or change treatment and can contribute significantly to improve patient outcome.

In another breast cancer study serum TK reflected the activity of two weeks of treatment with the CDK4/6 inhibitor palbociclib in combination with endocrine therapy. The results also demonstrate that serum TK correlate significantly with Ki-67 (Bagegni N et al, Breast Cancer Res. 2017 Nov 21;19(1):123) ■

You can hear more from Mattias in our free webinar, 'Predictive and Efficacy Biomarkers in Cancer Research' a joint presentation with Sue Burchill, Professor of Adolescent and Paediatric Cancer Research, Leeds Institute of Cancer and Pathology.

The full recording is available on our website:
www.biomarkers-congress.com/2018-webinar-recordings/

WEBINAR EXCERPT: Q&A SESSION WITH CONSULTANT BIOMARKERS SPECIALIST **JOHN ALLINSON**

John Allinson is Consultant Biomarker Specialist at Biologics Development Services.

John has over 40 years of experience in developing and working with biomarkers and has been an invited speaker on biomarker science at over 50 international conferences.

Why is there a problem in regulators producing, or not producing, a guidance document for biomarker assay validation?

The PK guidance was introduced to get a global standard across all laboratories at a time when there were so many different ways that were being used to validate assays. Introducing this concept was really positive and it had a massive impact on the comparability of the data that was then submitted to regulators, but it was, I believe, never designed to span into the biomarker world. This is because in the PK world we are really just trying to assess the pharmacokinetic parameters of the drugs being developed, whereas with different biomarkers with differences in physiological variability there's already a well-defined variation guidance out there in the clinical arena. This means that it's really leading to some significant issues and lack of consensus and much debate.

I remember when I joined the office for the lead paper back in early 2001-2002, even around the table of our key opinion leaders there was a wide variability. Interestingly and very fortunately we did have an excellent statistician on board who understood very well the differences between trying to define a clinically significant change in using biomarker assay compared to evaluating pharmacokinetic parameters. So, it has been a difficulty for most of the bioanalytical community who had, up until that point, had much of their work in the PK arena. Clearly, with the development of biologicals, that has also now moved into immunogenicity.

Interestingly, immunogenicity assays are all measuring biomarkers which means that guidance for immunogenicity came out quickly. This was significantly different from the PK guidance, but this didn't happen in the biomarker world in general for wet biomarkers that are normally present endogenously as opposed to an immuno response that is related to biological drugs. So, for anyone that has been present at any of the biomarkers meetings since 2000 onwards, I think that they will recognise the scope and degree of misalignment and maybe different opinions from different groups.

How could we validate biomarkers assays in high throughput platforms such as SWATH that are more in line with the discovery and innovation rather than diagnostics of those clinics and hospitals?

If we look at the original e-paper, we actually took what we called an exploratory evaluation approach, but I think in the biomarker discovery world it is somewhat different because we are looking to identify biomarkers that may have clinical significance in whatever disease area or context of use we're looking for. Therefore you often start off with non-quantative assays to do that and they're simply qualitative at whether the biomarkers are present or not. It's once you get beyond that point that you need to start very early looking at things more closely. If we identify biomarkers by looking at physiological variability, in at least a simplified way, so that we can demonstrate that if biomarkers are not originally there but then they become present, then that's very simple and a qualitative assay may do. However, if the biomarker is present and it seems to be increased, or if the reverse is true, then we need to make sure that we can evaluate the actual criteria that surrounds the assay performance to show statistical or clinical significance.

> *"Several biomarkers can be seen to be important with multiple therapeutic indicators and multiple pathology."*

So in terms of biomarker discovery I think that the platforms are a little different and that certainly the white paper and others have been designed to focus on quantitative biomarker assays. From my perspective, in the services that I have been providing to the drug development world, this really comes into post discovery, but we can certainly help in defining and assisting laboratories to validate those methods once they have been discovered. It has often been reported that that single biomarkers have often lacked in specificity or sensitivity from a diagnostic perspective because of the non-clinical specificity across multiple different therapeutic areas. Several biomarkers can be seen to be important with multiple therapeutic indicators and multiple pathology. I think it's a useful design experiment to identify the different biomarkers of interest to identify whether they are present or not and to identify whether they are going up or down. Then the validation process is really a continuing and developing process from the early stages where you may have very minimal validation to answer your first questions. Then as you find your biomarker development project going forward, the level of validation simply increases to interrogate the performance characteristics of the analytical method ■

This was an excerpt from the free webinar, 'Analytical Validation of Assays for the Qualification of Biomarkers'

The full webinar recording is available on our website:
www.biomarkers-congress.com/2018-webinar-recordings/

FORTHCOMING EVENTS

OXFORD GLOBAL

Biologics Series

APR	11th Annual Proteins and Antibodies Congress	London, UK
	5th Annual Peptides Congress	London, UK
	5th Biennial Biosimilars & Biobetters Congress	London, UK

Co-located Events

Genomics Series

MAY	2nd Annual Genome Editing USA Congress	Boston, USA
	Synthetic Biology USA Congress	Boston, USA
	2nd Annual Advances in Transgenic Technology USA Congress	Boston, USA
OCT	4th Annual Next Generation Sequencing & Clinical Diagnostics USA Congress	Boston, USA
	4th Annual Single Cell Analysis USA Congress	Boston, USA
NOV	10th Annual Next Generation Sequencing & Clinical Diagnostics Congress	London, UK
	6th Annual Single Cell Analysis Congress	London, UK
	4th Annual Genome Editing Congress	London, UK
	Synthetic Biology Congress	London, UK

Co-located Events

Cell Series

NOV	4th Annual Cell and Gene Therapy Congress	London, UK
	7th Annual Cell Culture and Bioprocessing Congress	London, UK
	5th Annual Stem Cell Congress	London, UK
	Biobanking and Regenerative Medicine Congress	London, UK

Co-located Events

R & D Series

FEB	13th Annual Biomarkers Congress	Manchester, UK
MAR	Formulation & Drug Delivery USA Congress	San Diego, USA
	Inhalation & Respiratory Drug Delivery USA Congress	San Diego, USA
MAY	4th Annual Formulation and Drug Delivery Congress	London, UK
	3rd Annual Inhalation and Respiratory Drug Delivery Congress	London, UK
	3rd Annual Advances in Immuno-oncology Congress	London, UK
JUN	19th Annual Drug Discovery Summit	Berlin, Germany
	6th Annual Discovery Chemistry and Drug Design Congress	Berlin, Germany
	2nd Annual Microbiome Discovery and Development Congress	Berlin, Germany
	2nd Annual Precision Medicine Congress	Munich, Germany
OCT	5th Annual Drug Discovery USA Congress	San Diego, USA
	3rd Annual Biomarkers & Precision Medicine USA Congress	San Diego, USA

Co-located Events

PharmaTec Series

SEP	16th Annual Pharmaceutical IT Congress	London, UK
	2nd Annual Artificial Intelligence in Drug Development Congress	London, UK
	Digital Health Congress	London, UK

Co-located Events

Biotech Investment Series

MAY	Biotech Investment Showcase and Start Up Slam	London, UK

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