International CLINICAL TRIALS

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epc European Pharmaceutical Contractor

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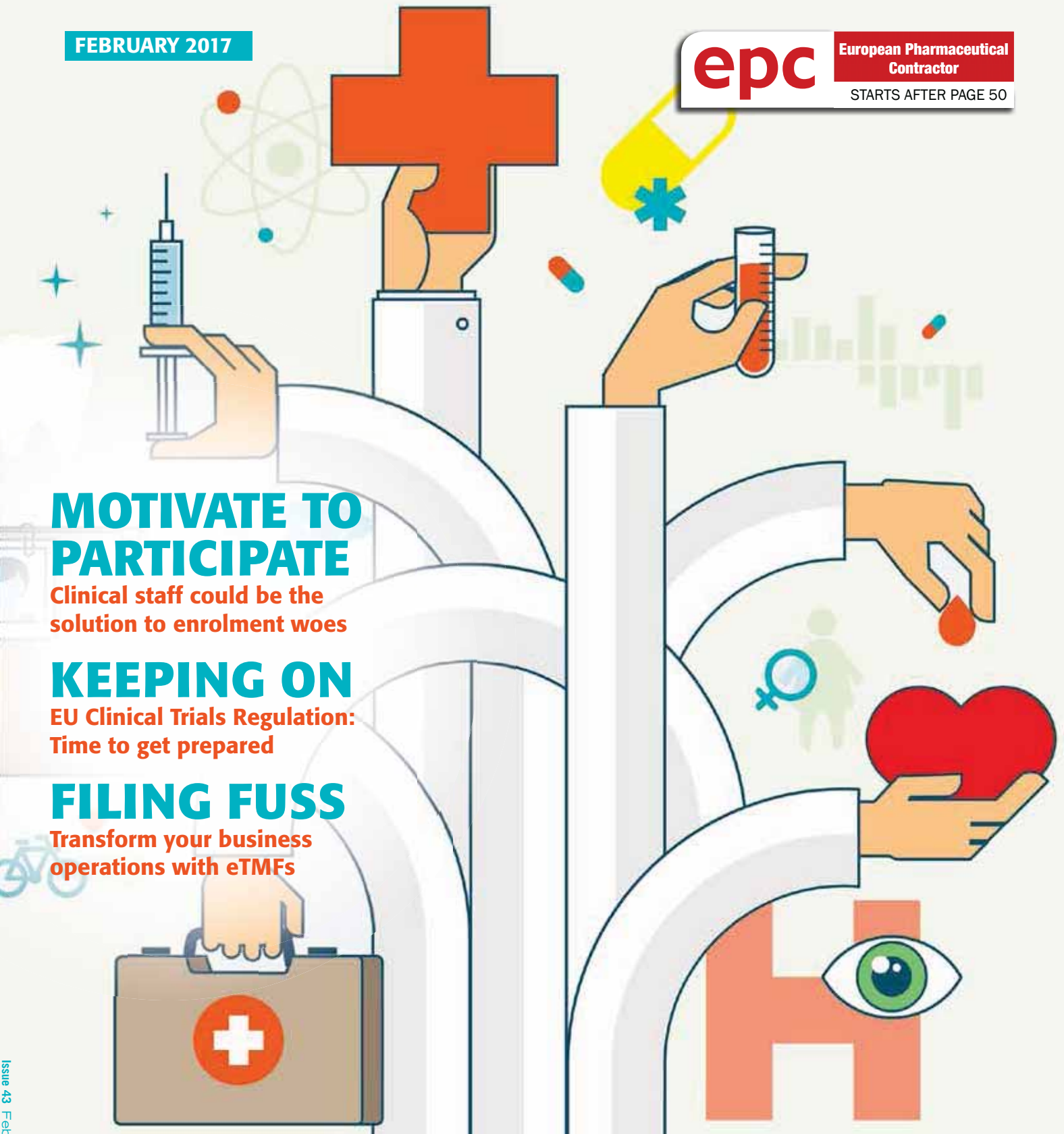

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Up in the Clouds

***ICT* talks to Michaeline Daboul about compliance challenges and how software solution MediSpend® makes it easier for life sciences companies to comply with the constantly evolving regulatory landscape**

***ICT:* Compliance is, and will always be, a major challenge across the pharmaceutical and life sciences sector. In your opinion, what are the most pressing hurdles for healthcare businesses to adhere to global laws, industry codes and company policies?**

Michaeline Daboul: The issue for organisations today is being able to quickly adapt to the evolving global laws that are impacting business activities while simultaneously containing expenditure and lowering the administrative burden on employees. The most pressing hurdles revolve around managing human workflows to reduce the risk of noncompliance with regards to industry laws that may result in costly investigations, litigation and expensive settlements. Ensuring compliance through business process improvement is one of the top challenges facing life science companies in 2017.

Furthermore, adherence to evolving laws, codes of conduct and global regulations are causing financial and administrative onuses. Current enterprise systems are not built to be flexible and adaptable to the changes required to comply with the aforementioned problems. In order to stay ahead, firms must not only address business processes, but also procedures that reduce cost as well as provide data that can be leveraged to manage risk and help to gain a competitive advantage.

Introduce us to the MediSpend platform; what does it hope to accomplish, and how does it differ from other compliance systems?

We wanted to take the difficulty out of adhering to regulatory laws – after all, our tagline is "Compliance is Mandatory. Complexity is Not." When we first built MediSpend, we asked ourselves how we could build a cloud-based software solution to be used by hundreds of firms, configured and modified quickly to meet the evolving laws and be inexpensive so that everyone can afford it.

Michaeline Daboul is the President and Chief Executive Officer of MMIS, whose team introduced MediSpend, the first SaaS compliance software solution for the life sciences industry. She has introduced disruptive technologies in the pharma sector for drug development, genomics research and compliance since 1985. Michaeline also mentors women in their technology careers and writes a blog for entrepreneurs and life science executives. She holds a degree in Biochemistry from Rutgers University, US.

While analysing the market and talking to organisations in order to identify the needs of the industry, we looked at both home-grown and existing systems in the market and determined that there was a major gap in solving the compliance problem. Home-grown systems are very costly to build and maintain, while third-party solutions tend to also be expensive and highly customised with long implementation timelines. At MMIS, we built a cloud-based Software-as-a-Service (SaaS) solution that is easy to configure and use – one that solves the compliance problem for our customers. MediSpend is the first and only multi-tenant SaaS compliance solution for life science companies and it also delivers on the cloud.

What are the reasons behind its creation, and how will it benefit pharma?

Biopharma, pharma and medical device businesses must comply with rules and regulations, laws and industry codes to manufacture and distribute their products. They have to ensure compliance to anti-corruption laws such as the Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act, as well

> **"Aggregating data from multiple source programmes – including enterprise resource planning, customer relationship management and home-grown legacy systems that were not designed to manage compliance processes – is a huge challenge for life science firms today"**

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Compliance Cloud for the Life Sciences

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Fair Market Value • Needs Assessment & Approval Workflow • Contracts Management
HCP Engagement & Monitoring • Activity Reports • Financial Analysis • Grants Management
Global Transparency Reporting • Compliance Audit & Monitoring • Business Analytics Dashboards

MediSpend Global Compliance Solutions

We help life science companies reduce compliance risk and eliminate manual business processes resulting in improved operational efficiencies. Ask us how we can help reduce risk and improve interactions with physicians and organizations conducting your clinical trials.

- **Industry Cloud Compliance for Life Sciences**
- **The first cloud-based compliance management system built specifically for the life sciences**
- **Cloud-based solutions to manage end-to-end interactions with physicians and organizations**
- **Full enterprise integration with 3rd party CROs**
- **Customer Success Team help companies move compliance to the cloud**

About MMIS | MediSpend

MMIS, Inc. is the creator of MediSpend a leader in cloud-based compliance software for the global life sciences industry. We are committed to customer success, developing innovative products and providing value to our customers and their organizations.

MediSpend customers range from the world's largest medical device, pharmaceutical, dental and emerging biotech companies. MMIS employees are based in the US and MMIS' customers are located in the US, Europe, Asia and Latin America.

Call us today and request real-life case study examples to demonstrate how life science companies are moving compliance to the cloud and using risk management and monitoring tools to gain a competitive advantage.

We can demonstrate enterprise cost-saving methods and how to leverage data from the upstream financial interactions between your company and physicians to create new business models that drive drug development innovation and good business practices.

To learn more, contact us info@medispend.com. You can follow Michaeline at: Twitter: @mmispresident, LinkedIn: www.linkedin.com/company/mmis-inc or http://medispend.com. Call us at +1 (888) 731-7322 x 8200.

MEDISPEND
Global Compliance Platform

as global transparency laws like the European Federation of Pharmaceutical Industries and Associations, Loi Bertrand and US Open Payments. We created the MediSpend Global Compliance Platform to help companies streamline business workflows with key controls in order to reduce risk and provide transparency at all levels.

Aggregating data from multiple source programmes – including enterprise resource planning, customer relationship management and home-grown legacy systems that were not designed to manage compliance processes – is a huge challenge for life science firms today. Most of the practices used today are not cloud-based but custom, hosted solutions built internally or by third parties. A cloud-based solution allows users to gather data in real time to monitor compliance, while also leveraging the information for business activities.

It is evident with new technologies and innovations that the industry is undergoing significant changes. What are the implications of this?

After watching the market evolve since 2011, I believe we are now experiencing a transformation and companies are moving their business applications to the cloud. The good news is that MediSpend is already there and can be integrated easily with current enterprise systems like Oracle, Quintiles, Salesforce, SAP, Veeva and many others.

In short, the repercussions are mostly positive with increased visibility into business activities through data monitoring and analytics, thereby decreasing the risk of noncompliance through:

- The early identification and remediation of bad behaviours
- A reduction in the time it takes employees to complete tasks
- Compliant reporting becoming cloud-based and thus saving time and money as well as increasing accuracy

Our vision is coming into reality today and we are watching companies implement MediSpend, retiring legacy systems and giving employees back their weekends! We really subscribe to the philosophy 'more for less, for more'; when you build a product or service that proposes more features for less money, you can offer it to more people. Our customers range from startups to the world's largest life science companies.

You started out as a small technology startup, but are now one of the leading global providers of cloud-based SaaS solutions. How was this achieved?

I started a successful company in 1999 whose mission was to help pharma companies educate doctors on the latest evidence-based data to improve patient care. We helped those organisations improve by educating doctors through the internet to deliver educational websites, portals and online continuing medical education programmes.

Back then, the rules governing conflicts of interest and transparency did not exist as they do today.

We continued to follow the evolution of enhanced regulations, governing the manner in which life science firms interacted with healthcare providers (HCPs). As compliance burdens increased for our existing customers, we leveraged our technology expertise to build solutions to meet their needs. As we are a technology company building programmes for pharma organisations, we decided to marry the subject matter expertise that we had in the sector with our software development talent and we created a solution to enable companies to reduce risk and comply with global laws. As a result, we switched our business model and created MediSpend, which was launched in 2011.

Are you looking to further develop the MediSpend platform? What potentials do you see for the product in the future?

MediSpend is considered a market disrupter for transparency reporting and has replaced home-grown and first-generation systems. When it was first introduced, it was designed to aggregate and capture all payments and transfers of value – considered 'downstream spend data' – made to HCPs and organisations. MediSpend Aggregate Spend captures the information, validates it and then produces the required government reports.

Over the past two years, we have worked closely with our customer base to better understand the business problems related to doctor engagement – the 'upstream' workflow. During our discussion, we realised that there was no cloud-based SaaS solution in the market that managed the entire doctor engagement process for our customers and the larger life sciences market. Companies engage and work with doctors and organisations in many ways through activities and services provided by HCPs. Whether it is a clinical trial or an educational speaking engagement, advisory board, or new product development, firms work with and pay doctors in the normal course of business. Managing the entire process from needs assessment to doctor validation, qualification, contracting, engagement and payment is an enormous manual undertaking. As you can imagine, there are a lot of areas where a manual process fails, so monitoring business behaviour is key to reducing risk and possible violations of laws like the FCPA, UK Bribery Act and so forth when interacting with doctors.

In 2016, our development team worked closely with our customers to build MediSpend Engagement Mananger, a cloud-based solution that manages the entire upstream process of doctors' engagement through the downstream aggregate spend analysis and transparency reporting, that will be released in March 2017. The MediSpend Global Compliance solution is the only end-to-end, SaaS cloud-based compliance solution for life science companies.