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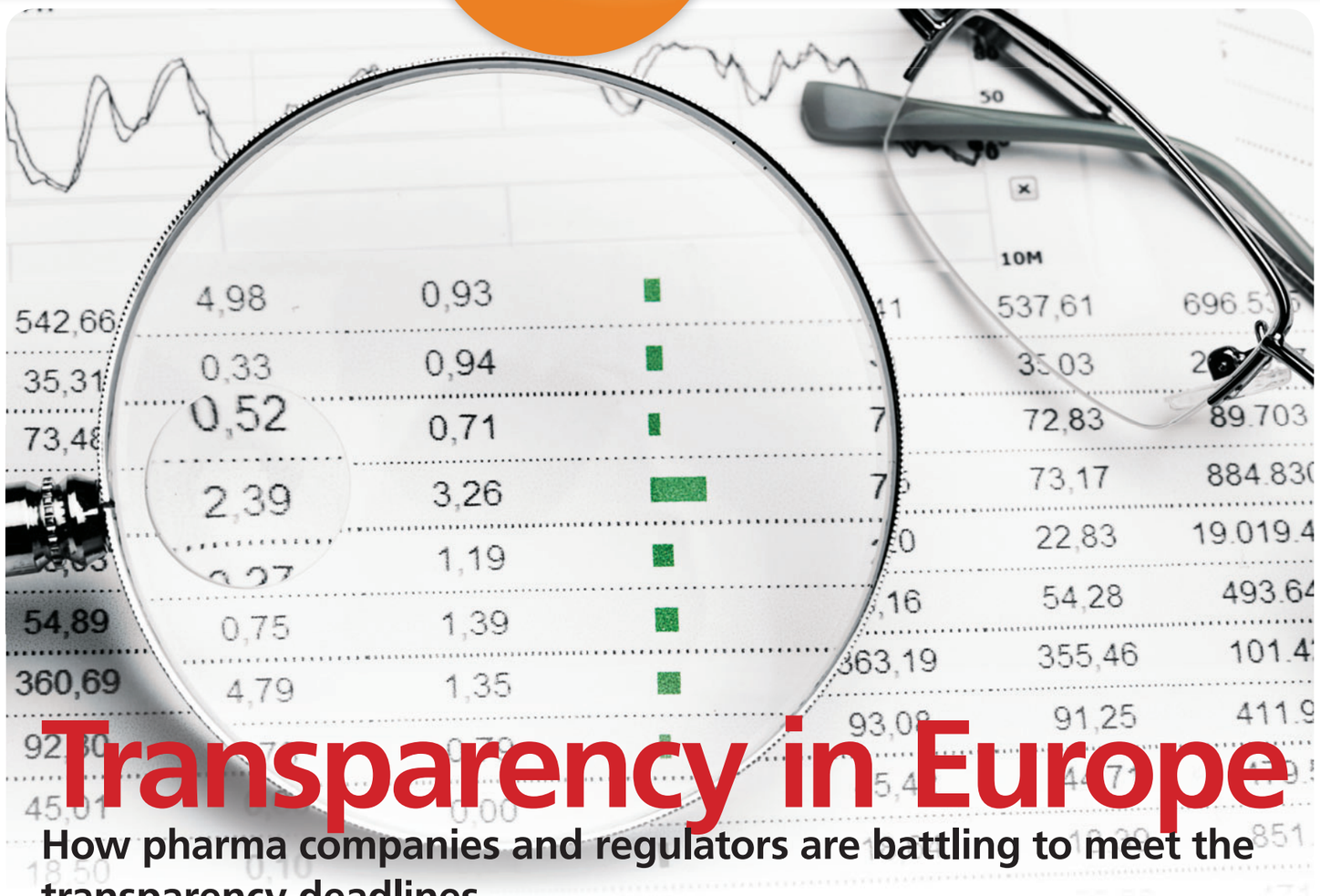
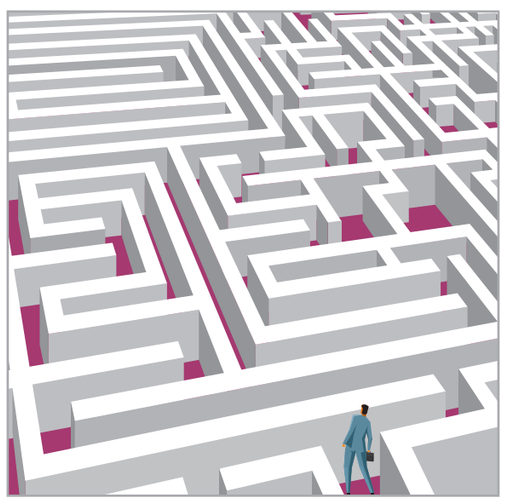


Transparency in Europe

How pharma companies and regulators are battling to meet the transparency deadlines



The EMA's Transparency Dilemma

The European Medicines Agency thought it might be back on the road to salvation when Guido Rasi started ordering greater transparency in 2011. But instead it looks to be on the road to hell, writes Peter O'Donnell.

The European Medicines Agency has been bending over backwards to get transparency right.

The European Medicines Agency thought it might at last be back on the road to salvation when Guido Rasi swept into town in 2011 and started ordering greater transparency in the Agency's operations. He was determined to seek a new type of trust with the Agency's various publics — and particularly with those who had been most vocal in attacking it for secrecy. The Agency has ever since been bending over backwards to get transparency right.

But instead of the road to salvation, the Agency finds itself yet again on that road so well-paved with good intentions — the road to hell.

Its crowning achievement in transparency —proactive release of clinical trials data— was only weeks from finalization as we went to

Cristian Baitg/GettyImages

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press. But EMA is again under fire — and, paradoxically, for subverting transparency with the very mechanism — pro-active release — that it is planning to introduce to boost transparency.

The criticism has sprung simultaneously from at least two separate points.

The first to hit the headlines was the European Ombudsman, with a public statement on May 16 that the Agency's new scheme looked as if it was going to undermine transparency.

The second — on the same day — came from scientists linked to the Cochrane Institute and the British Medical Journal, and accused the Agency of a "U-turn" from earlier promises, and of seeking to impose gatekeeping controls that would slow rather than speed access.

The European ombudsman investigates complaints about maladministration in the institutions of the European Union. The current incumbent, Emily O'Reilly, took over the post last year, and has been energetic in her pursuit of complaints — as well as avid in her endorsement of transparency.

The current European ombudsman, Emily O'Reilly, has been avid in her endorsement of transparency.

She enthusiastically welcomed the recent European Parliament vote backing new clinical trials rules with ambitious provisions on data access, and congratulated the parliament "for having successfully steered this legislation through to a very positive outcome."

In recent weeks, the EMA invited her to a meeting to discuss the way it was finalizing its plans for pro-active access to clinical trial data, but she declined. Instead, the Agency sent her its latest draft of how it envisaged its new scheme operating — on May 7. On May 13, she wrote to Rasi outlining concerns that the plans would limit rather than widen access, contrary to its earlier aims.

On May 16 she released her statement, saying that the Agency "is planning to limit access to clinical trial data by imposing strict confidentiality requirements and by allowing data only to be seen on screen using an interface provided by EMA, as well as imposing wide restrictions on the use of such data." She said the approach could "undermine the fundamental right of public access to documents established by EU law."

She focused on what she saw as over-restrictive protection of data defined as confidential because of its commercial significance, and conflict with existing EU legislation on access to documents. If the Agency "considers that its proposed new policy provides the same level of transparency," O'Reilly said in her letter, "it is obvious that such an assumption would not be well-founded."

Also on May 16, Tom Jefferson, a reviewer at the Cochrane acute respiratory infections group in Rome, Italy, and Peter Doshi, an assistant professor of pharmaceutical health services research at the University of Maryland in Baltimore and associate editor at BMJ, issued a statement claiming that the Agency plans represented "a stunning and surprising reversal."

The Agency, caught on the back foot by the simultaneous assaults, pointed out that the documents it had shared were drafts, not yet finalized.

It insists it is not trying to limit citizens' rights to information. Its new policy was intended as a supplement to, and not a replacement for, the rights of access that all EU citizens already enjoy under existing legislation.

"Our objective is to facilitate

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proactive access to clinical trial data," the Agency said. The new EMA policy would go further than the existing rules, since it will offer data proactively, rather than merely in response to requests. And the new system will operate alongside the existing procedure, which anyone will remain free to use.

The irony in much of this episode is that the Agency, by its own exercise in transparency, has triggered the flurry of attacks. It provided the draft documents to the ombudsman and it consulted with academia and journals in a bid to avoid criticisms of acting in secrecy

These are now being used as incriminating evidence in the criticisms levelled at it. In short, the EMA is damned if it does, damned if it doesn't.

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Compliance Without Tears

Andy Bender and Geert van Gansewinkel outline steps to staying ahead of transparency in Europe.

There are several advantages to the pharmaceutical and medical device industries in Europe developing their own codes...

The European compliance and transparency landscape has changed rapidly over the last couple of years. With the rise of pan-European as well as a myriad of country-specific regulations, the complexity of the compliance environment is growing.

Although there is one common Europe-wide set of guidelines provided by the European Federation of Pharmaceutical Industries Association (EFPIA), there are also a lot of local versions which apply to specific countries. These vary from legislation (such as in France, Portugal, Denmark and Slovakia) to industry codes (such as the Netherlands and the UK). It is expected that local variations will continue to exist going forward.

Unlike in the U.S. however, most of the reporting

Hong Li/GettyImages

regulations in Europe have been — with the exception of France and some smaller countries — driven by industry. In fact, in Europe, pharmaceutical companies under EFPIA have been preempting the initiatives that were taken by the U.S. federal and state governments and have been developing their own transparency code.

Additionally, the European Organization of Medical Device Companies (EUCOMED) is following EFPIA and is working on a transparency code for next year.

There are several advantages to the pharmaceutical and medical device industries in Europe developing their own codes, one of which is consistency across the continent.

While having some Europe-wide consistency in compliance guidelines and regulations is an advantage for the European pharma sector, there is much more the sector needs to do from an internal perspective to change the culture of compliance. In order to stay ahead, European life sciences executives must go beyond the mindset that the compliance reporting technology they may have just purchased will be the Holy Grail for compliance sustainability and transparency nirvana.

> Unlike in the U.S., most of the reporting regulations in Europe have been driven by industry.

In order to effectively implement the technology across 33 countries, executives need to bring along local management in each of the countries and convince them why compliance and transparency reporting is good for business. To do that, fundamental changes from an organizational, structural and cultural perspective need to take place.

Cultural change as a compliance driver

Over and above the challenging compliance landscape, there is additional complexity impacting transparency relating to the way companies are organized internally in Europe.

Unlike in the U.S., where there is usually a central organization making enterprise-wide decisions, life sciences companies in Europe typically have a combination of a regional center with local country organizations.

Even though the level of decision-making that occurs centrally vs. locally differs on a company to company basis, it is not uncommon for companies to have strong local decision making authority.

Given these internal organizational realities, the key to success in implementing any compliance program and reporting system in Europe will be the extent to which the compliance business owner can get the buy-in of management and staff throughout the company, which will require employee behavioral and cultural change. Getting all of the stakeholders to buy into a new culture and providing the transparency reporting data can be quite a challenge, particularly since they don't understand the value of this to their local business.

In our experience, European life sciences companies that have been successful with developing a sustainable transparency and compliance program have focused on three key elements:

- Focusing on the soft side of change, viewing compliance not as a technology project to be implemented, but emphasizing change in individual behaviors.

- Placing equal — if not more — emphasis on the spend capture side as having a reporting solution is good, but

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is of little value if the wrong data is being collected

• Keeping track of what is next, shifting focus early on to likely upcoming challenges once initial benchmarks are reached in meeting current reporting deadlines,

The soft side of change

Eight lessons learned for executing a soft change program for enhancing compliance effectiveness within European life sciences organizations include:

1. Start with an assessment of current compliance practices, systems and processes, followed by the development of an implementation roadmap. A comprehensive understanding of the types of processes and systems being utilized and what marketing, sales and medical activities take place in each of the different countries should be assessed. A best practice is to perform a gap assessment; outlining gaps between local requirements and current practice, and develop recommended actions and a related implementation roadmap on the basis of that assessment.

It is not uncommon for companies to have strong local decision making authority.

2. Ensure senior management support from the beginning. Implementing a change program can take anywhere from 6–18 months, requiring many different countries and departments to work together. Senior management involvement is needed to provide and approve all necessary resources, to enable decisions to be made on a timely basis and to keep the project team on time, on budget, and on scope (OTOBOS).

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3. Establish a Steering committee.
The steering committee should be established early on. It should serve as a strong governance and core team representing different sides of the business and include central management in the area, as well as local management, who can become the champions after a successful program pilot is executed.

In addition, the steering ommittee provides resources needed, sets priorities for local country management and drives implementation of consistent processes and best practices across countries.

4. Institute a pilot program before pan European implementation.
While some smaller-sized companies in Europe may opt to do a full scale, cross-continent compliance program launch, for most European life sciences organizations, particularly larger companies with more complex systems, initially implementing a pilot version before a full roll-out of the transparency reporting solution or compliance program is a typical approach.

There are numerous reasons for going the pilot route, but a principal one is that it is easier to manage resources to make the implementation successful, given the scope of the project. Also, when first piloted to individual countries, these countries can be used as champions after a successful implementation, convincing the remaining countries to adopt the program.

5. Assign the program to a business owner, not the IT organization.
Selling management on the added value of collecting spend and use the information for strategic decision making purposes. The spend capture, collection and reporting process can actually provide new insights into the business and help adjust and guide business strategy and direction. Additionally, it's ultimately the business users that will need to change their behavior. Therefore, it's critically important for the compliance program to be assigned to a business owner and not to the IT function.

6. Appoint a central Project Management Office and Change Management Office to drive execution.
Most companies underestimate the vastness of the program and so never assign any centralized, accountable function for overseeing its implementation.

A specific compliance programs PMO needs to be created for taking charge of this responsibility along with the creation of a Change Management Office or function (if not already in existence) for partnering with the PMO in carrying through the needed organizational changes to ensure compliance program robustness, effectiveness and success.

7. Organize the project in distinct workstreams, making sure relevant work packages are addressed.
As the compliance implementation plan is developed and internal cultural and structural changes are made to ensure robust execution of the program, by apportioning the program into defined work streams, every functional, topical and issue-related aspect can be addressed, including processes, training, system deployment, master data management and data privacy.

It has been our experience that most companies overly focus on the technical aspects of implementing a transparency reporting solution or a compliance program, while forgetting that there are many related processes that need to be changed in each of the participating countries.

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8. Establish a clear set of principles that will guide implementation.
Companies should establish a defined set of guiding principles for how the compliance program is implemented and stick to them to ensure non-interruption, with the only exceptions being for legal or regulatory developments that emerge. Setting these principles allow for interpretation of the implementation guidelines and decentralized decision making during the execution of the program in the local countries.

Companies need to harmonize spend collection processes and systems first...

Don't put the reporting cart before the spend capture horse

For many different reasons, companies want to have a consistent pan-European, or better yet, global reporting solution.

To accomplish this in an efficient manner, companies need to harmonize spend collection processes and systems first in order to get the right spend into the system.

This means that local management might have to adapt some of its local processes and systems to comply with the best practices of a global solution, typically driven by a central or global management team. Having said this, the solution needs to be flexible enough to adapt to local practices and reporting requirements.

The benefits go beyond implementing best practices, but actually make their processes more efficient. For instance, many companies are currently collecting additional information for reporting purposes so they learn more about the current state of their business and help better analyze and inform strategic decision making. Additionally, many companies are using the compliance exercise as an opportunity to upgrade their systems and invest in making their processes more efficient.

Challenges beyond the reporting horizon

After a successful implementation of the reporting solution, it is likely that new questions will arise. Best practice companies are already preparing in advance for these questions, and to the extent possible, are including them in their current implementation plan.

From our discussions with life sciences companies in Europe, we see three topics emerging.

1. Fair Market Value and KOL scoring.
Companies will be concerned about how much they are reporting and about whom. Even if national governments might not have the resources to analyze the reported data, competitors and public advocate groups will have an interest in the information reported.

Therefore, we see companies focusing on Fair Market Value (FMV) for HCP and HCO services like ad boards, speaker programs, and consulting services as well as services provided for CME, IIS, IIT and all other HCOs. As an extension to developing an FMV methodology and rates, we see companies develop Key Opinion Leader (KOL) scoring methodologies, allowing them to distinguish between different levels of KOLs for FMV payment purposes.

Companies are using the compliance exercise as an opportunity to make their processes more efficient.

2. HCP Consent
Companies are starting to consider sending reporting

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data to the HCP before the reports are due to be submitted in order to obtain buy in and sign off. France's Sunshine Act, as a matter of fact, currently has similar requirements, and other countries are following. Collecting the data in time and reporting this to the HCP will be a challenge. In addition, addressing questions and concerns from HCPs based on the pre-reported data, will require an efficient and timely process.

3. Due Diligence/Background Checks

Similar to FMV, after they are reporting on HCP/O spend, companies will be concerned about who they are doing business with. Several companies have started a process of vetting HCP/Os through a number of methods including risk analysis, and third party risk assessments, background checks via external background screening services, self-certifications on information provided by the HCP/O and requests for audits, and requesting additional information on the background of the HCO/HCP.

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Clinical Trials in Europe: The Die is Cast

The die still needs some refinement, some polishing up, some detail clarification.

Politicians and health campaigners are celebrating the final agreement of the EU's new clinical trials rules. But the European drug industry is not so euphoric, writes Reflector.

After more than 18 months of often-acrimonious debate, the European Union's new clinical trials rules were agreed in April.

European health commissioner Tonio Borg said: "This endorsement brings us one step closer to ensuring an environment that is favorable for conducting clinical trials, with the highest standards of patient safety, for all EU member states".

He said "one step closer" advisedly. Because although the die is cast by the vote, the die still needs some refinement, some polishing up, some detail clarification. And this is where the discussion will now move.

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The outline shape

As Borg summarized it, what the new regulation brings

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is simplification of current rules, a 'one-stop' portal and database for submitting applications, a quick and flexible assessment procedure, a simplified reporting system and clearer, simpler rules for running multinational trials.

For the sake of political correctness, industry offered a lukewarm welcome to the new framework.

He highlighted the advantages for patients — "the main beneficiaries of clinical trials" — and for research institutions and companies — saving nearly $1bn a year in regulatory costs. He acknowledged the merit of "keeping clinical research within EU borders", where the $25 billion spent every year on pharmaceutical innovation and health-related research development "is vital for the EU economy".

UK MEP Glenis Willmott, who steered the legislation through the European Parliament, said it will make trials more transparent, ease cross-border cooperation "to make clinical trials larger, more viable and more reliable", and "boost efforts to develop special treatments, such as for rare diseases".

For health campaigners, the EU vote is a triumph of "putting public interest ahead of commercial interests". The new law will "ensure clinical trials are registered and their results reported", said AllTrials, which has been lobbying energetically for greater transparency, and "will change the future of clinical trial reporting.

The only criticism from AllTrials is that the EU has still not gone far enough, because it relates only to future drugs. It is calling for "all clinical trials, past and present, to be registered and results reported".

It's an ambition shared by Dr Ben Goldacre, author of the controversial book Bad Pharma, who said: "Doctors and patients simply cannot make informed decisions about which treatment is best, when the evidence on the treatments they are using is still being routinely and legally withheld."

Drug industry caution

The European drug industry, however, has not welcomed the EU agreement as euphorically as the politicians. The European Federation of Pharmaceutical Industries and Associations (EFPIA) greeted the vote with a call for "collaboration" in implementing the new rules — not a very subtle code for "careful how you go about this!"

Echoing Borg's observations about the importance of keeping trials in Europe, EFPIA delivered a none-too-oblique warning: "The global market for clinical trials is becoming increasingly competitive and Europe runs the risk of losing its status as an attractive environment for clinical trials research in the face of strengthening competition."

For the sake of political correctness, industry also offered a lukewarm recognition that the new framework "will help foster a more harmonized approach to clinical trials in the EU, with a single submission and overall streamlined assessment process".

But it wasted no time in adding that "some of the initial objectives...have been only partially achieved" — noting the need for improved efficiency of the process for controlling trials.

The critical issue, it went on, is that the authorities interpret the new regulation "in a manner that respects patient privacy, the integrity of regulatory decision-making, and incentives for companies to make long-term investments in biomedical research."

Richard Bergstrom, director general of EFPIA, stated:

“There is still work to be done. The success of this legislation will depend on how it is applied in practice. It will be essential to collaborate with relevant stakeholders and ensure they have the opportunity to provide input. This is a must if we are to achieve a system that will foster the innovation we need to improve patient outcomes.”

Devil in the detail

In EFPIA’s view, success now depends largely on the legislation’s implementation at member state level.

This next stage, it says, will show how far collaboration is promoted between ethics committees and what efforts are made to allow assessment of clinical trial applications in the shortest time frame possible.

One of the underlying EFPIA concerns is that if the maximum timelines in the new rules become the norm rather than the exception, it might take 156 days to get approval for a clinical trial on

In EFPIA’s view, success now depends largely on the legislation’s implementation at member state level.

a biotech product — compared to 30 days in the United States.

Another determinant of success will be how efficiently the clinical trials database and the associated electronic portal function — and how soon!

Helpfully, EFPIA says it is “ready to contribute as a strong stakeholder partner to support its development and implementation”.

A long list of EFPIA recommendations — made to the European Commission, the European Medicines Agency and the member states — also includes action to ensure greater cooperation between ethics committees.

It suggests the creation of ethics committee networks as a step in the right direction. EFPIA is also concerned at what it sees as imprecise wording that could allow a member state to decline authorization for a clinical trial: objections based on the regulation’s vague grounds of “safety and data reliability and robustness considerations” will have to be carefully monitored, EFPIA says, “to avoid disharmonized approaches to the detriment of patients, investigators and sponsors”. And provisions on notifying the start and end of a trial are so complex in the regulation that this risks becoming an administrative burden creating duplication of work for sponsors.

The die may well be cast, after debates that lasted nearly two years. It could take as long to agree on the necessary polishing, too.

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Transparency and Clinical Trials: Toward 2016

Chris Hamilton explains how clinical trial sponsors can prepare for Europe's upcoming clinical data transparency regulations.

Clinical trial sponsors need to evaluate whether they are prepared for the upcoming legislation in 2016.

A recent initiative by the European Medicine Agency (EMA) on data transparency has been finally passed into draft law by the European Union, requiring that detailed summaries of clinical trials are published in a publicly accessible database once marketing authorization is granted. Sponsors could face strict fines for not complying.

Izabela Habur/GettyImages

Also, in March 2014, the EMA published the first summary of a risk management plan (RMP) for a newly authorized medicine, stating "the Agency will pilot the publishing of RMP summaries for all newly centrally authorized medicines during 2014 and at a later stage will start producing RMP summaries for previously authorized medicines".

The RMP will be a publicly

available document that describes all that is known and unknown about a drug's safety and what actions will be taken to monitor the drug on the market and mitigate any risks.

Clear traceability of clinical data is imperative to satisfy not just the EMA but also EU law.

These latest developments signal a significant step towards greater clinical data transparency in the European Union. The ultimate aim is to make it mandatory for sponsors to respond to reasonable requests from the public to access the data, not just the results, collected during clinical trials. For this reason, clinical trial sponsors need to evaluate whether they are prepared for the upcoming legislation which is anticipated to take effect in 2016.

The EU states its objective in the opening section of the legislation, "In a clinical trial the rights, safety, dignity and well-being of subjects should be protected and data generated should be reliable and robust."

Ensuring clear traceability of clinical data is therefore imperative to satisfy not just the EMA but also EU law. Being mindful of this requirement from Phase I will pay dividends for sponsors later on. CROS NT is a strong advocate of centralizing data from the outset because it has seen so many of its customers benefit from this approach in terms of efficiency, cost savings, standardization and regulatory approval.

For sponsors selling the product license to a larger pharmaceutical company a centralized approach can enhance the value of the intellectual property because everything is in the one place, fully traceable and due diligence ready.

Preparing your data — biometrics

Centralize clinical data from the start.
If one study team is assigned to statistical trial design, data management, data analysis and medical communications from the start, common data standards can be applied throughout the drug development process. Continuity of team members creates a consistent style of medical communications and important collaboration between statisticians, data managers and medical writers. All data are stored in a central data warehouse and/or archive which avoids having to keep track of multiple repositories.

Centralizing clinical data in the early phases of drug development facilitates better integration of studies across all phases with common assessment methods, uniform traceability of data as well as the centralization of study metrics and study reports.

Ensuring traceability for regulatory submissions.
In order for data to be transparent to the public, it must also be traceable. Implementing CDISC standards helps both traceability and cross analysis of datasets. There must be clear traceability from analysis results, to analysis datasets, and to SDTM datasets.

There are two types of traceability: data-point traceability and metadata traceability. ADaM datasets allow for the creation of variable or observations that are not directly used for the statistical analysis but support traceability.

For example, re-allocation of data may happen for early termination visits in accordance with the Statistical Analysis Plan whereby both original visit name and re-allocated visit name are kept within the ADaM dataset. Metadata traceability includes documentation required to clearly describe information that already exists in the

SDTM database together with algorithms and methods used to derive an analysis result.

Preparing your data — integrating technology

Clinical data visualization. Clinical data visualization can be an important component for sponsors conducting trials in Europe who need to make more informed decisions and make sense of clinical data which could eventually be shared publicly. Conducting a trial generally leads to data being spread across multiple databases including EDC, CTMS, ePRO, safety databases, etc and if a centralized approach is not employed, such databases can be spread across multiple vendors and countries.

Data visualization tools facilitate drill-down and click-through to multiple levels of detail, allowing for the analysis of specific subsets and sub-populations. Customizable dashboards allow the clinical team to create ad hoc reports on site performance, data quality, safety and efficacy, drug supply, patient management etc.

> Data visualization tools facilitate drill-down and click-through to multiple levels of detail...

Using data visualization tools, clinical leaders can see information that is beyond the capability of the CTMS report set. They also facilitate Risk Based Monitoring which vastly improves data quality and cuts monitoring costs. Most importantly, they allow clinical study teams to make crucial decisions from the information and trends revealed during the study rather than at the end.

Centralized storage. If the EU legislation takes effect, sponsors will need to be able to produce data for publication in an EU database. If all trial data are already centralized then they will be indexed, traceable and transportable. This means they can be easily transferred to a publicly accessible database. Centralized storage can produce additional benefits like greater efficiency and cost reduction. Review cycles can be reduced with standardization. Sponsors can also avoid paying for multiple global library set-ups, programming macros and validation checks.

Chris Hamilton is Global Head of Business Development & Marketing, CROS NT.

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Biopharma services organization PARAXEL named Dr Sy Pretorius as Chief Scientific Officer. Dr Pretorius currently serves as the company's Corporate Vice President and Worldwide Head of Early Phase, and will continue in that capacity in addition to assuming his expanded responsibilities.

Cobra Biologics (Newcastle-under-Lyme, UK) appointed Dr Daniel C. Smith as Chief Scientific Officer. Dr Smith has spent the last four years with the bioProcessUK team at the HealthTech & Medicines Knowledge Transfer Network (KTN), driving the innovation agenda for biologics bioprocessing in the UK as a Knowledge Transfer Manager.

GenSight Biologics (Paris, France) announced the appointment of Jean-Philippe Combal as Chief Operating Officer. Dr Combal worked at Fovea Pharmaceuticals from 2006 to 2011, as Vice President, Director of Development, then as Vice President, Strategic Marketing for the Ophthalmic Division of Fovea-Sanofi.

USA

Morris J. Birnbaum, M.D, Ph.D, is to join Pfizer in July as Senior Vice President and Chief Scientific Officer of the Cardiovascular and Metabolic Disease (CVMED) Research Unit. Dr Birnbaum was Professor of Medicine and Associate Dean for Biomedical Core Resources at the Perelman School of Medicine at the University of Pennsylvania. In 1994 he was appointed the Rhoda and Willard Ware Professor of Diabetes and Metabolic Diseases and an Investigator in the Howard Hughes Medical Institute.

Executive search company RSA, appointed Elizabeth McCabe as Head of RSA North America. Prior to joining RSA, Elizabeth started Artis BioMedica, a boutique search firm focused in the life sciences.

Oncology-focused company Curis, Inc. (Lexington, MA) named Ali Fattaey, Ph.D., as the company's President and CEO and as a member of its Board of Directors. Dr Fattaey formerly served as the company's President and Chief Operating Officer.

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PAAS 2014 — PATIENT ADHERENCE AND ACCESS SUMMIT

June 17–18, 2014: Philadelphia, PA

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PAAS moves adherence programs from theory into action. This year's event puts on spotlight on programs achieving ROI on adherence.

For further information, visit http://www.cbinet.com/conference/conference/pc14116#.UwzE3f3nffM

SPEED TO THERAPY

August 12–13: Philadelphia, PA

What the Affordable Care Act means for speed to therapy and how to be prepared for the new delays that could arise, and how to optimize the specialty pharmacy and manufacturer relationship.

For further information, visit http://www.cbinet.com/conference/pc14289#.U2D00f2dzfM

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TRANSPARENCY AND AGGREGATE SPEND

August 18–20: Washington, DC

The essential meeting place for pharma, biotech and medical device executives to meet andshare best practices and innovative solutions to address the requirements surrounding federal, state and global HCP spend reporting.

For further information, VISIT HTTP://WWW.CBINET.COM/CONFERENCE/PC14156#.UWZFSV3NFFM

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INTERNATIONAL PHARMACEUTICAL COMPLIANCE CONGRESS

October 21–22: Brussels, Belgium

CBI's International Pharmaceutical Compliance Congress offers the opportunity for global companies to come together, share ideas, network and learn from one another. The International Compliance Congress will cover topics such as transparency, FMV, third party due diligence, the role of compliance and many other issues faced by the industry.

For further information, visit http://www.cbinet.com/conference/pc14084#.U2Dz_f2dzfM

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Global Digest

Mission

Pharmaceutical Executive Global Digest provides industry intelligence so managers in the international pharmaceutical community can advance their business, management and marketing practices to gain competitive advantage. PEGD interprets the current and future challenges the industry faces and enables pharmaceutical professionals to overcome them with cost-effective, time-saving solutions.

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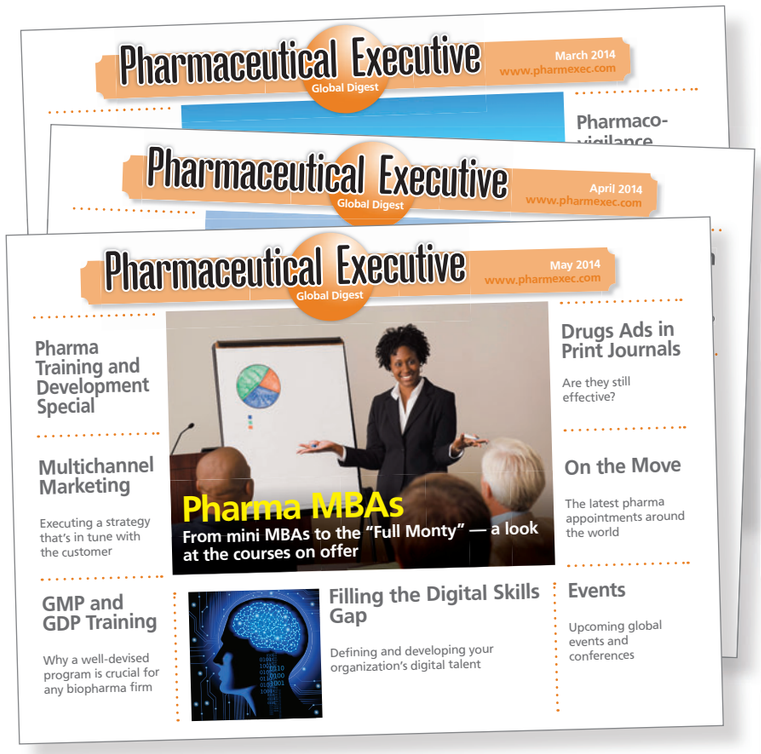

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