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LETTER FROM THE EDITORS

By Pooja Shah, Dora Amene, Alena Attiyah & Zeb Adomako-Mensah

Welcome to the pre-conference edition of PIPELINE. It’s the third and final PIPELINE of 2019 and we hope the editions we have brought to you this year have been insightful and beneficial to your development, both professionally and personally. We would encourage all our members to get in touch with us if there is a topic you would like to see covered in future editions, as we want to ensure we create the most valuable resource for our members.

Talking about offering our members valuable resources and development options, online bookings are still being taken, until 26th September, for the eagerly awaited 2019 PIPA Conference at Stratford Manor, Stratford-Upon-Avon on 2nd and 3rd October 2019. Use this link to guarantee your place and for further information about this year’s exciting conference programme: https://www.pipaonline.org/Conference-2019.

Last year’s conference, held at Legoland Conference Centre in Windsor, attracted over 100 delegates, exhibitors and speakers on each day. The topical presentations ensured lively discussions and the exchange of ideas, with delegates taking advantage of the multiple networking opportunities. Just as a reminder, PIPA members who attend conference have access to electronic copies of the conference presentations after the event, but they are not made available to the wider PIPA membership. Be sure to also get your tickets to the networking dinner on 2nd October 2019, as these nights are not to be missed!

In this busy edition of PIPELINE, we’re delighted to present you with a wide range of articles, including an introduction to the PIPA committee’s workstreams. We think it is important for our members to understand who is in the committee so you can contact us with any questions or suggestions you may have, and to also understand what the committee does and how we work. We would like to take this opportunity to reach out to you all for any suggestions, proposed events, activities and training courses etc. that you would like us to provide.

One of our committee members, Tom Nichols, has provided his insight into starting up his own company, for those of you who have had that urge to go it alone. Tom discusses the highs and lows since he made the brave decision himself. For those of you who prefer to work within a company setting, Axess have written a brilliant article on effective performance development reviews and how to have successful and productive discussions, both as an employee and employer.

Our Vice-President, Janine Gavin-Poulter, has written an article for PIPA members on the management of standard operating procedures for your company processes which should have you gliding through inspections. Talking about inspections, our President, Ejaz Butt, has provided his insights on the most common audit findings and how to effectively address them.

Dr Susan Brook from Cancer Research UK has written a fascinating article on basket and umbrella trial designs in oncology, and the pros and cons of each.

CompliMed have provided an insightful article looking at compliance criteria for medical symposia; the areas that cause confusion, the associated compliance risks and ways to mitigate some of these.

We’ve listed here only a few of our many topical articles that we have collated for this edition, and we hope you enjoy reading it as much as we have enjoyed putting it together. Just to add, the updated 2019 PIPA MI Standards Guidance Document will soon be available electronically via the members section of the PIPA website. The committee have worked tirelessly on this document, in collaboration with industry experts, to ensure the guidance document is up-to-date and in line with current legislation and working practices.

As always, we welcome your feedback and encourage you to interact with us and the other PIPA members via our online platforms.

On that note, we would like to end by wishing you all a brilliant Autumn and a merry Christmas and a very happy new year.

Until the next edition of PIPELINE, at the start of 2020, we hope you all have a wonderful end to 2019 and continue to strive for excellence over the course of the year!

If you want to make a contribution to PIPELINE, please feel free to contact us at journaleditor@pipaonline.org.
This article will discuss the most common audit findings for medical information (MI) and pharmacovigilance (PV) and provide an overview of how to best engage with stakeholders, subject matter experts and divisional managers to work with quality assurance in order to address these common findings.

Audit findings

Audits sit alongside regulatory inspections as an important activity that can influence change (there isn't a whole GVP module dedicated to it for no reason!). The conduct of an audit is a critical element of a PV system which extends to all 'touch points' of PV activities, such as MI.

Commonly referred to as observations, issues or findings, the outcomes of an audit are often the result of a number of deficiencies, gaps, inconsistencies or non-compliance with a range of formalised or legal instructions or standards. From an internal company perspective, such standards include operational procedures, contractual agreements and policies. External influencers include legislation, regulations and guidelines.

An auditor will interview audit participants and review documentation to assess and verify whether a company is performing its obligations, and conducting activities, in a way that reflect those standards to the best of its abilities. Any activities that fall short, or are completely absent, as compared to the standards are transcribed as audit findings.

Findings are also categorised on severity, in order to give each finding some weight. This allows the company to determine the order in which the issues should be resolved. Further information regarding these categories can be found in Section IV.B.2.3.2. of GVP Module IV (https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-iv-pharmacovigilance-audits-rev-1_en.pdf).

In summary, however, they are Critical, Major and Minor.

Frequently occurring findings

This is not an exhaustive list, but a few examples selected to cover the two disciplines that our PIPA members predominantly follow: MI and PV.

Medical Information:

1. Lack of quality control over notes taken from calls that were transcribed into an electronic system — so any data that gets transcribed or transferred from one source to another would need quality control (QC) to ensure accuracy and that all information has been captured.
2. No defined timelines for retention of voicemail messages — retention of voicemail is important even for a reasonable limited duration as these are classed as “source” and should be retained for a certain period to ensure they have a source to go back to when required.
3. Lack of compliance with GDPR for managing patient data — it is important to ensure that any communication containing patient information is transferred adequately (i.e. through a secure channel that is controlled with an audit trail) or encrypted if being emailed.
4. Missed adverse events (AEs) in enquiries — lack of thorough review of medical enquiries to assess for AEs.
5. Testing of out of hours capabilities — to ensure any out of hours facilities or staff undergo routine testing to ensure services are running appropriately. For example, ensuring there is an adequate system (e.g. email and voicemail) in place to capture enquiries received outside of normal office hours.

Pharmacovigilance related:

6. Lack of vendor oversight — any outsourced PV activities still form part of the sponsor’s Quality Management System and it is their responsibility to ensure adequate oversight by routine activities such
as reconciliations, compliance monitoring, quality assessments and audits.

7. Absence of PV monitoring of solicited programs — since such programs are usually being performed by divisions outside of PV, there is the risk of inadequate monitoring of PV activities, thereby increasing the risk of non-compliance.

8. Business Continuity Plan (BCP) did not adequately cover PV activities — usually there will be a crisis management or BCP on a corporate level, but sometimes these do not detail any information for PV activities, which is a key critical part of the PV system to ensure PV activities can continue.

9. Distribution of risk management material prior to regulatory approval — with so many participants involved in the development and dispatch of risk management material, it is very easy to inadvertently skip steps. One step that gets frequently skipped is the distribution of material that has been submitted to the authorities for review, but has not yet come back as approved.

10. Handover from QPPV to Deputy during absence not well defined — there are procedures and tools in place to ensure the QPPV has the ability to conduct their role adequately. Sometimes, however, these processes do not include the deputy QPPV in key areas, or the tools to be made available to the
deputy, should they need to step into the role as back up. There is also often an absence of testing of the handover between the QPPV and deputy QPPV, to ensure that it is smooth and without problems.

Agreeing a plan to address the findings

The first step would be to agree to the findings themselves! We need to be mindful that the more people involved and impacted by the findings, the more a difference in opinions will be met. It is important for the Quality Assurance team to take the lead and the initiative on managing the findings and communicating these to the divisions responsible for the related activities.

Assuming that there are no further negotiating points with the auditor, it is important to proceed with a plan to address the findings by conducting a thorough investigation of the root cause, corrective actions and preventative actions and how this can be presented to the auditor with applicable timelines and evidence to back up the actions.

Operations teams, such as MI and PV, will work closely with QA to provide all the information necessary around the individual findings. There are often challenges with achieving agreement with team members, and also with management, around the nature and importance of the findings themselves. One great tool is the actual observation table from the audit report. A good auditor will always explain the finding in a very practical manner to allow the reader to understand the issue well, and provide a brief background on what impacts would be observed if any issues were to be left unaddressed.

During the conduct of the audit itself, there are also interviews held with a member of the MI and PV team. Often, this individual can be present at the closing meeting of the audit where the issues are shared. Having that person involved in the discussions can add strength to getting agreement on the findings and the potential impact of ignoring them. As identified in the above section, all findings are referenced against a standard. Non-compliance with those standards can lead to further problems and potentially more serious implications outside of the audit (e.g. in an inspection).

Once buy-in is agreed with all participants, a thorough investigation has been conducted, and the root cause(s) identified and recorded, then a Corrective And Preventative Actions (CAPA) must be developed. When developing this, it is important to keep the finding in mind at all times so that the focus is on the actual finding itself. It is very easy to drift away from the scope, leading to a risk of the CAPA being rejected.

Most likely, the corrective action was performed immediately at the time of discovery of the non-conformity and that is easy to record. However, if it hasn’t, then not only does it need to be addressed as soon as possible but also, again, this needs to link in with the finding in question. The preventative action must be realistic, with realistic timelines, and must also agree with the finding. It should be sufficient in answering the issue with the long-term goal of ensuring that it will not reoccur.

An audit must be perceived as a positive exercise, and if team members are educated on the process and its benefits then the audit conduct becomes more enjoyable (dare I say!) and the results can be welcomed as an opportunity to make a positive change.

An auditee once said to me that “this audit is basically free QA for us!”, in the sense that they have had the opportunity of a gap-analysis exercise conducted on their processes to identify and iron out issues that probably would have gone unnoticed during routine work. This type of attitude is a good approach when positively embracing an audit situation, and educating your department to think the same way could set the foundation for making improvements to the way you work.
There have been significant advances in both understanding the molecular biology of cancer and in innovations in drug development technology, thus enabling development of new, targeted treatment options for patients with specific molecular abnormalities (biomarkers). Very effective molecularly-targeted drugs have been developed, e.g. for lung cancer patients with anaplastic lymphoma kinase fusions and epidermal growth factor receptor mutations. However, identifying and screening biomarker-selected patients for clinical trials is challenging and resource-intensive. Thus, new strategies are needed to match patients to therapies from which they are most likely to benefit. This approach requires efficient clinical trial designs for evaluating these therapies, with swift, multi-biomarker patient evaluation. Newer biomarker-driven trial designs have the potential to address these issues (Figures 1 and 2).

Historically, oncology trials were histology focused (e.g. lung cancer study, breast cancer study, etc.), but focussing on genomic abnormalities may be more predictive of drug sensitivity.

A basket trial enrols patients who have the same genetic mutation (molecular target), regardless of tumour type, then all patients receive the same therapeutic agent that targets that specific marker, thus facilitating a targeted approach across multiple cancer histologies (the ‘basket’).

‘Umbrella’ studies evaluate multiple targeted therapeutic strategies in a single type of cancer histology. An umbrella trial enrols patients who share a common tumour type (the ‘umbrella’) and performs molecular marker testing for a range of potential targets. Patients are then assigned to a study arm based on the presence of a mutation matched to a potential drug for that marker. Sometimes one arm is included for patients without a specific marker being evaluated. Arms may open and close as new targets and treatments are identified so many potentially active drugs can be tested simultaneously (Renfro and Sargent, 2016).
Basket Trials

Advantages

- Can be more efficient and less costly than multiple histology-specific trials.
- Only need to develop one assay for the trial thus potentially reducing time between initial diagnosis and/or eligibility confirmation, cohort assignment and initiation of treatment.
- Statistical power can be reached with fewer subjects and in less time than a traditional approach, as the data from different arms can be amassed (Cunanan et al., 2017). This enables early termination of arms unlikely to show efficacy.
- Offer a range of therapeutic agents to patients across a broad range of tumour types, potentially including patients with rare molecular features not otherwise studied in trials.
- Can include adaptive rules for adding or dropping arms.
- Can be extended to include a randomisation step/control treatment within each basket.

Disadvantages

- Requires reliable preclinical models to assess the mechanism of action in various tumour environments.
- Analytic performance of assays for biomarker determination should be similar across baskets - assays with low specificity or low sensitivity for resistance variants may dilute the treatment effect (Renfro & Sargent, 2017).
- Assumes that molecular profiling may be sufficient to replace histological tumour typing. (Sometimes, histological tumour type predicts response to treatment more strongly than the biomarkers or mutations comprising the studied cohorts) (Renfro & Sargent, 2017).
- May require large number of drugs and biomarkers.
- Patients are regarded to have comparable expected response rates across tumour types, even when they have different tumours (e.g. breast versus colon) which are known to have different prognoses.
- Development of multiple assays more complex than with a single biomarker (reference: www.cancertherapyadvisor.com/home/cancer-topics/general-oncology/basket-trials-advantages-and-limitations/).
- Some baskets may have small sample sizes if mutation is rare.
- Single arm sub-studies generally require a high tumour response rate endpoint.
- Challenging to define historical controls across diseases.
- Complex statistical methodology to address design challenges.

An example of a basket study is the NCI Molecular Analysis for Therapeutic Choice (NCI-MATCH) study in solid tumour or lymphoma patients who progressed on standard therapy (Mullard, 2015; http://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/nci-match). The study opened in 2015 with initially 10 treatment options. As of June 2019, it has 12 active histology-independent marker-based treatment arms. Each treatment is an independent single arm phase II study with objective response rate as the primary outcome.

An update published in 2017 (Harris et al.) stated that as of July 2017, 5,963 tumour samples from patients across the United States had been screened. Patient accrual to each arm has been variable. Of all the treatment arms, 8 of the 30 reached the minimum patient accrual goal of 35, and some have been expanded to allow for up to 70 patients. The sample size for each treatment arm is relatively small and the patients referred to the trial tend to be heavily pre-treated, making broad applicability limited.

Umbrella Trials

In contrast to basket trials, the umbrella trial evaluates many treatments within a single tumour histology. A patient could therefore be eligible for multiple arms (e.g. the tumour contains multiple aberrations).

Advantages

- Can draw conclusions specific to one tumour type and therefore less prone to chance.
- Tumour heterogeneity present within a given cohort mirroring clinical practice.
- Can randomise to targeted versus non-targeted treatments within a cohort, thereby evaluating the drug more objectively, as any observed benefit may be attributed to the marker (Renfro and Sargent, 2017).
- Prognostic versus predictive markers can be assessed.

Disadvantages

- Feasibility. Further sub-classification of some already-rare tumour types by molecular mutations may lead to poor recruitment and slow trial progress.
• Randomisation generally requires larger cohorts so increasing trial duration.

• Treatment landscape of the tumour type studied may change during the trial, e.g. new standard of care may require changing the control arm.

An example of an umbrella trial is Lung-MAP (Ferrarotto et al., 2015) in patients with previously treated advanced squamous cell lung cancer (NCT02154490) (Figure 3). The estimated enrolment is 10,000 patients (clinicaltrials.gov).

Initially, parallel randomised phase II/III sub-trials were to assess targeted therapy versus standard of care chemotherapy, docetaxel. A separate cohort was for ‘non-matched’ patients not eligible for target cohorts who tested positive for an anti-PD-L1 inhibitor.

One initial cohort (c-MET-positive) closed early for toxicity. In March 2015 the FDA approved nivolumab in the same patient population as the new standard of care. Therefore, modifications to Lung-MAP were implemented: the control arm (docetaxel) was dropped. New objectives in the non-match arm were introduced (single versus combination immunotherapy and a sub-study for PD-1/PD-L1-resistant patients).

Summary

Basket and Umbrella study designs offer major benefits for developing new targeted treatment approaches in oncology. They have the potential to increase efficiency in drug development compared to traditional approaches in cancer trials, especially with rarer cancer sub-types, possibly leading to earlier approval for commercial use.

However, the success of these newer trial designs is also reliant on robust statistical methodology, expert pharmacogenomic contribution and reliable validated assays, the development of which is crucial.

References:


Syn et al., Evolving landscape of tumour molecular profiling for personalized cancer therapy: a comprehensive review in Expert Opinion on Drug Metabolism & Toxicology. June 2016 DOI: 10.1080/17425255.2016.1196187


Mullard A NCI-MATCH trial pushes cancer umbrella trial paradigm Nat Rev Drug Discov 2015; 14: 513–515


Dr Susan Brook
Clinical Development Physician, Cancer Research UK
The 2019 PharmaTimes Medical & Scientific Excellence Awards aim to recognise and reward those within the Medical Information sector, by offering a platform for candidates to share best practice and to prove they’ve got the skills to be successful. Winners will be awarded a coveted pharma trophy and be recognised in front of the national medical affairs community.

Categories available for entry include:
- Medical Information Professional of the Year
- Medical Information Lead of the Year

Also available:
- New Medical Science Liaison of the Year
- Experienced Medical Science Liaison of the Year
- New Medical/Scientific Advisor of the Year
- Experienced Medical/Scientific Advisor of the Year
As the impact of disruptive technology bites deeper into our everyday working world, what trends are we likely to see in Medical Information (MI)? Is increased globalisation/regionalisation of Medical Information functions, and the evolution of those departments, also changing the nature of MI jobs?

Although the pharmaceutical industry tends to be a late adopter of technological trends, some companies are already exploring chatbots and the possibility of using artificial intelligence to augment the tasks involved in providing an MI service. These tools can potentially transform the role of MI personnel. Are we already starting to see job roles within the MI community evolve to meet customer, and therefore business, demands?

To answer these questions, Angeles Flores, Senior Medical Information Manager, Lilly Spain, and I ran an industry survey during September 2018 which was extended to January 2019. Angeles Flores presented the initial survey results at the Drug Information Association European Medical Information & Communications conference in November 2018. The combined survey attracted 71 responses. 23 incomplete responses and 3 duplicate entries were excluded. The final dataset was 45 respondents from at least 30 companies. Almost half represented national MI teams (from Europe, US, Canada, Australia, New Zealand or Brazil), 30% from regional teams (mostly EU or EMEA regions) and 20% from Global MI teams.

The survey covered 3 key areas (see Figure 1 for more details):

- Existing traditional MI roles (e.g. responding to MI requests, creating standard content or MI management)
- New or emerging roles – actual or planned
- Future of Medical Information, including changing healthcare practitioner (HCP) or patient customer needs

Emerging New Roles

Almost a quarter of the respondents (N=10) had created new types of roles within the last 2-3 years, especially in regional MI teams. Of these respondents, 40% planned to create more new roles in the next 1-2 years in areas...
such as innovation, specialist capability like insights, data analysis/visualisation or technology implementation.

Of the respondents who had not created new roles recently, a third plan to introduce new roles within 1-2 years.

The survey stimulus was the creation of 3 new roles in the Lilly Medical Information Europe team:

- Communication Leads - based in the local affiliates - who focus on communication between countries and centralised services;
- Launch Leads, to focus on product launch preparation;
- An Innovation Lead, to energise the innovation culture in MI.

Other companies had roles including:

- Global MI Technology & Knowledge Management;
- Operations Manager for vendor oversight, inspection readiness and MI practice consistency;
- Call Centre Management, insights and analytics;
- Diverse responsibilities such as database management, congress booth leadership, content creation.

Compliance and Customer Insights are now seen as core MI competencies.

Drivers for these new roles include factors such as:

- Increased globalisation;
- More new channels investigated or adopted;
- Greater use of vendors requiring robust oversight and compliance;
- Leveraging insights from data analytics;
- Regulatory restrictions and impact of the European General Data Protection Regulation;
- Drive for content innovation and global content creation strategy.

This doesn’t mean that headcount is necessarily expanding (specifically stated by some respondents) but the types of roles are already changing within MI.

Shifting Customer Needs: Better, Faster, Easier

We also asked about observed changing customer requirements. As their needs shift and change, so we need to change to reflect (or anticipate) these challenges. HCPs want more online/virtual information and immediate (or at least faster) answers than we currently provide. There’s a lot of interest in offering alternative channels (e.g. WhatsApp or Live Chat). We also need to use different content formats to improve health literacy or tools that help patients directly. Providing more information on adverse event frequency was a specific example.
Patients’ needs show similar trends: faster answers, alternative channels, virtual contact (like Live Chat), personalisation and online information, available proactively or automated. They want understandable advice (including off-label information). More digestible formats, including information visualisations or patient specific materials, were also desirable. Obviously we can only provide information, not specific advice about our medicines and devices so we need to find a way to clearly and precisely present product label-related information in a way that patients with variable educational levels can clearly understand.

Understandably, the survey showed a high level of interest in technological solutions which deliver enhanced customer experience. However, companies recognise that they struggle to get answers to customers in the time frames that customers want.

**Ready for the Future? Developing MI Capability Needs**

Not all companies had the headcount for dedicated roles to meet these challenges and future opportunities. Instead, they are expanding existing job roles to include these new responsibilities.

Respondents were specifically asked what additional capabilities would be needed in the near future. The two dominant areas are:

- Data analysis/insights
- Being more flexible and open minded to changes

MI professionals need to have enhanced data analysis skills (including intermediate level Excel skills), and expertise in information visualisation and creating customer insights. Communications skills include greater use of video (presumably how to create video content) and Live Chat interactions. Exploring other new channels and being able to successfully exploit technology will be essential. However, the more traditional capabilities of business acumen, operational management and project management were also mentioned.

**Conclusions**

Much has been written about how jobs will have to radically change due to technological advances and disruptive business models. Medical information provision is no exception. The survey showed that some companies are already changing MI roles with enhanced data analysis and multi-channel capability to reflect rapidly changing customer needs.

Are you or your team already making the adjustments necessary to evolve? We need to look outside of our own reactive industry to seed greater innovation. To quote Zig Ziglar: “Success occurs when opportunity meets preparation”!

What are you going to do differently today to make sure that you will flourish tomorrow?

**Acknowledgements**

Thank you to PIPA for publicising the survey to their membership which boosted the survey participant rate. Data analysis and visualisations were done by Robert Leighton. The survey was run in conjunction with Angeles Flores, Senior Medical Information Manager, Lilly Spain. Please contact Sharon for more information via sharon@sharonleighton.co.uk.

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Sharon Leighton
Sharon Leighton Consultancy Ltd
Advance your career with Professional Training courses

PIPA offers its members peer-reviewed training courses, designed and led by industry experts, for professional development in Medical Information and Pharmacovigilance. These courses include assessments and validation and participants are awarded a certificate on completion of the course. With prices starting at £40+ VAT (online) and £350 + VAT (face to face), the courses are exceptionally good value.

New courses are currently in development and will be added to the training programme throughout the year.

For more details visit: https://www.pipaoonline.org/Training/PIPA-Training-Programme

Face-to-Face Training

- Pharmacovigilance System Master File (PSMF) - June 2020
- Foundation Skills in Medical Information - September 2020
- Foundation Skills in Pharmacovigilance - September 2020
- Affiliate Management in Pharmacovigilance - October 2019
- Advanced Pharmacovigilance Skills: Current Hot Topics - April 2020
- Advanced Medical Information Skills - April 2020
- How to Interpret Clinical Data—Statistics and Clinical Trial Design in Practice - date on request
Do you have trouble sleeping?
Do you over-eat?
Do you have low moods?
Do you suffer from stress?
Are you a lady of a certain age heading towards or going through the big ‘M’?
Do you have low libido, sexual or reproductive problems?

These are just a few of the issues that hormones play a key role in. Optimum hormone balance is crucial to overall health and well-being so it is important we support them as best we can through what and how we eat.

**Hormones have a lot to answer for**

“Weight gain, mood swings, fatigue, and low libido aren’t diseases that can be “cured” with a quick injection or a pharmaceutical. Most of these problems can’t be permanently solved by eating less or exercising more. They are hormonal problems. They mean our bodies are trying to tell us that something is wrong.”

Dr Sara Gottfried MD, Author of The Hormone Cure: Reclaim Balance, Sleep, Sex Drive and Vitality Naturally with the Gottfried Protocol
Hormones are chemical messengers secreted by a series of glands around the body which make up the endocrine system. They travel around the body in the blood stream to organs and tissues to tell them what to do. They control many daily functions including:

- Metabolism
- Respiration
- Growth

There are a lots of normal hormone changes during life including puberty, pregnancy, breast feeding, menopause, sexual arousal, stress response, glucose regulation, emotional response, sleep cycle and many more. Your hormones work hard and interact with each other to maintain homeostasis. However this careful balance can be disrupted by:

- Chronic Stress
- Poor gut health
- Vitamin D deficiency
- Lack of sleep
- Too much or too little exercise
- Environmental toxins
- Unhealthy lifestyle choices
- Genetics
- Age

### So how can what we eat help?

What we eat not only fuels our bodies, but the micro nutrients are the raw materials our body uses to produce and utilise our hormones effectively.

When hormones become disrupted or imbalanced the body tells us by expressing a symptom which, if it continues, can cause issues over time.

Here are some of the imbalances that commonly occur, the symptoms that may be expressed plus the micro nutrients that can help to support this issue.

<table>
<thead>
<tr>
<th>Imbalance</th>
<th>Symptom</th>
<th>Micro-nutrient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low testosterone - Testes/Ovaries</td>
<td>Sexual dysfunction, vaginal dryness, low libido, erectile dysfunction, impotence</td>
<td>Vitamin C, Selenium, Vitamin D, Zinc</td>
</tr>
<tr>
<td>High cortisol - Hypothalamic Pituitary Adrenal (HPA) axis</td>
<td>Digestion issues, weight gain, increased appetite, lack of concentration, fatigue, acne, high blood pressure, headaches, anxiety and sleep issues</td>
<td>Magnesium, B Vitamins, Vitamin C, Omega 3s</td>
</tr>
<tr>
<td>Low oestrogen - Ovaries</td>
<td>Vaginal dryness, irregular periods, low mood, depression, anxiety, weak bones, hot flushes and weight gain</td>
<td>Phytoestrogens, Magnesium, Zinc, Calcium, Vitamin D, B vitamins</td>
</tr>
<tr>
<td>T3/T4 imbalance - Thyroid Gland</td>
<td>Metabolism issues: weight gain or loss, hair loss and thinning, fatigue, anxiety, disrupted sleep and concentration</td>
<td>Selenium, Iodine, Vitamin D</td>
</tr>
<tr>
<td>Low melatonin - Pineal Gland</td>
<td>Sleep issues, restlessness, insomnia, fatigue and brain fog</td>
<td>Magnesium, B vitamins, Zinc, Omega 3s</td>
</tr>
<tr>
<td>Insulin resistance - Pancreas</td>
<td>Fatigue, increased appetite, brain fog, weight gain, high blood pressure</td>
<td>Chromium, Magnesium, B Vitamins</td>
</tr>
</tbody>
</table>
How do we add these nutrients to our diet?

Let’s look at what foods are the best source of those hormone friendly nutrients.

**Fatty acids (especially omega 3s)**
- Oily fish (especially salmon, mackerel, sardines), avocado, coconut oil, egg yolk.

**B Vitamins**
- Wholegrains, meat including liver & kidney, eggs, legumes, nuts & seeds, leafy greens, fish, dairy.

**Vitamin C**
- Kiwi, bell pepper, orange, strawberry, broccoli, sprouts, mango, tomato, spinach, pineapple, grapefruit.

**Vitamin A**
- Butternut squash, sweet potato, kale, spinach, carrot, dried apricot, broccoli, egg yolk, liver.

**Vitamin D**
- Mushrooms that have been in the sun are the only plant based source, fish, egg, dairy.

**Zinc**
- Lamb, beef, chicken, pumpkin seeds, chickpeas, cacao powder, cashews, yoghurt, mushrooms, spinach.

**Magnesium**
- Spinach, chard, samphire, dark chocolate, pumpkin seeds, almonds, black beans, avocado, dried figs, yoghurt, banana.

**Iodine**
- Seaweed e.g. nori, wakame, kombu, cod, plain yogurt, iodised salt, shrimp, egg, tuna, dried prunes.

**Selenium**
- Mushrooms, brazil nuts, spinach, oats, fish (especially tuna, sardines, salmon), meat, eggs, brown rice, sunflower seeds, lentils.

**Chromium**
- Brazil nuts, pear, shell-fish, tomato, broccoli, grapes, potato, garlic.

**Phytoestrogens**
- Organic soy and fermented soy products e.g. miso, tofu, tempeh, edamame, flax seed (linseeds), oats, broccoli, carrots, lentils.

Top tips for supporting hormone health through diet

There is a lot of crossover in the food sources of the micro nutrients we need to support the endocrine system and general hormone health, so when eating a varied nutrient dense wholefood diet they will be in plenty supply.

It is more import to take a broader view and build a framework for a long term hormone friendly eating plan. Here are some top tips:

**Have a balanced macro plate** - Ensure your eating plan is based on a balance of complex unrefined carbohydrates, quality protein and healthy fats as they all play a role in hormone health, satiating us and maintaining the homeostasis which is crucial for hormone balance.

**Choose low glycaemic load (GL) foods** - When choosing your carbohydrates, include complex unrefined carbohydrates which have a low glycaemic load. E.g. beans and pulses, whole grains, fibre-rich vegetables, nuts & seeds. They are metabolised more slowly and so do not cause blood sugar spikes so help to control blood sugar levels and ward off insulin, adrenal and cortisol imbalance.

**Increase healthy fats** - Good fats (especially omega 3 fatty acids) are very important for hormone health as they help to synthesise hormones and keep the brain and nervous system healthy. The endocrine system is largely controlled by neurons sending messages to the pituitary gland and the rest of the endocrine system.

**Include pre & probiotics** – Gut health is an important factor in hormone health: not only is it crucial for the effective and efficient metabolism and absorption of nutrients (you are only as healthy as the nutrients you absorb!) there are certain microbes which help to synthesise hormones too. Prebiotics are the food that feed the good bacteria in the gut, for example insoluble fibre from fruit and vegetables, and probiotics are live cultures that can help to populate the gut with beneficial bacteria found in fermented foods, for example sauerkraut and kefir. So increasing fibre and including fermented foods can be very beneficial.

**Reduce inflammatory foods** - Everyone is different but common inflammatory foods include processed foods, gluten, refined oils, and, for some, nuts and seeds, nightshade vegetables etc. It is best to reduce inflammation as this puts a stress on the body by increasing cortisol and potentially causing a whole cascade of hormone disruption.

**Reduce stimulants** - Caffeine and alcohol, for example, stimulate the body and so cause an increase in cortisol and impact the adrenal glands. Alcohol has also been associated with oestrogen dominance.
Reduce toxins - Reducing environmental toxins like chemicals in cleaning products and toiletries as well as harmful plastics is recommended as many of them are Environmental Endocrine Disruptors (EED) which can imitate hormones and block or alter normal hormone function.

Hormone friendly recipe

Super Seed Bread

This quick and easy nut and seed loaf is light in texture and dense with nutrients. Full of protein and fibre as well as hormone supporting nutrients including phyto-oestrogens, vitamin E, B vitamins, calcium and zinc. Rich in boron from the nuts and seeds, this further helps with hormone-related symptoms such as brain fog, reduced bone density and muscle mass.

Makes 1 x 2lb loaf

Dry
20g chia seeds, ground
20g flax seeds, ground
100g ground almonds
100g free from fairy gluten free flour
50g flaked almonds
50g pumpkin seeds
20g sesame seeds
1½ tsp bicarbonate soda

Wet
4 eggs
1 tsp apple cider vinegar
1 tbsp honey
1 tbsp white miso paste
50ml avocado or olive oil
50ml almond milk
garnish: flax seeds and pumpkin seeds

Method
1. Preheat oven 175°C and line a 2lb loaf tin.
2. In a large bowl combine the dry ingredients and mix well.
3. Blend the wet ingredients in a blender until smooth and creamy.
4. Combine the wet and dry ingredients and mix well before pouring into the loaf tin.
5. Sprinkle with seeds then place in the oven and bake 30-35 mins.
6. Leave to cool before slicing.

Notes:
Do not substitute any of the seeds for sunflower seeds as they react with bicarbonate of soda and will go green. The bread will keep in the fridge for about 5 days or you can slice and freeze

Allergens:
Nuts, seeds & soya

For information on Jo’s workshops, courses and recipes go to:
http://www.timetonourish.co.uk
https://www.facebook.com/timetonourishuk/
http://www.facebook.com/groups/timetonourishtribe
https://www.instagram.com/timetonourish/

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https://www.diabetes.co.uk/
https://www.healthline.com/
https://www.hormone.org/
https://www.saragottfriedmd.com/
https://draxe.com

Jo Keyes
Natural Chef
Founder of Time to Nourish
MANAGEMENT OF SOPs

By Janine Gavin-Poulter

Standard Operating Procedures (SOPs) are the backbone of almost every industry. They guide employees on how to perform their tasks effectively and, most importantly, in compliance with company standards and regulations. That being said, SOP management is not always run as efficiently and effectively as companies would like - often due to several factors, such as:

• No assigned person(s) responsible for the management of the SOPs
• The quantity of required SOP documentation
• The level of detail in the SOPs
• Lack of clarity and stakeholder input

Creating and updating SOPs can often feel like a lengthy and overwhelming exercise but until the update has been completed, the company is at risk whilst undergoing an audit or inspection. The risks of not having adequate SOPs is a significant liability at the time of the pre-approval audit/inspection, so ensuring appropriate SOPs are in place reduces the risks and, more importantly, the findings.

If you are the person(s) responsible for the creation, review and management of SOPs, or your company does not have this process in place, I hope this article provides some key insights and useful information you can use in your workplace.

SOP Management

The management of SOPs includes a variety of roles, from the creation of new SOPs to the review of existing ones, from cross-functional working with stakeholders to the completion and distribution of the SOP training and, yet still, there is so much more to take into consideration. There is version control, archiving of documentation, routing the SOPs to the correct individuals for review and sign off, naming conventions and accessibility of the SOPs. The list goes on. However, below are some key steps that can be taken when coordinating the SOP throughout the SOP cycle:

Fundamentals of the SOP

• Determine the requirement for a new SOP or for the revision of an existing SOP.
• Determine the scope, roles and responsibilities of the SOP.
Appoint a named person to coordinate the SOP cycle, known as the ‘author’: this person will write the SOP.

Identify who else needs to be involved in the review and authorisation of the SOP.

When writing/updating/reviewing the SOP, understand the target audience and what they should be getting out of the SOP.

Consider whether the SOP is sufficiently detailed. Is it limited in any way? Is the correct terminology being used?

**Identify the essential structure of the SOP**

When creating a new SOP, it is important to take into consideration the core components of the SOP and identify the:

- Purpose of the SOP
- Scope
- Definitions/Abbreviations
- Person(s) responsible for the SOP
- Procedures
- References
- Changes
- Appendices.

**SOP Naming Conventions**

- Naming documents is the key to having consistency across SOPs. Naming conventions should be easy to follow and understood by all: keep it practical and avoid using obscure terms.

- They should be easily identifiable by:
  - SOP reference number
  - Document name
  - Version identifier (if applicable)

**Source the global SOP**

- If available, the author should source the global SOP to ensure that they are aligned with company procedures and processes.

**Writing the SOP**

Whether creating a new SOP, or updating a current SOP, it is important to ensure that they all read the same way for consistency, and to distinctly describe the different processes in each department. There are two problems when writing an SOP: too much information or not enough. If the SOP is vague, people can’t use it and if the SOP appears to waffle and is complex, people can’t, or simply won’t, follow it. The level of detail is crucial here, and may differ depending on the process. Try to focus on the ‘need to know’ and the ‘nice to know’ information.

For example: is the process a business-critical process? who will be using the SOP? how often will this SOP be followed? does it contain enough information so the task can be completed correctly and efficiently?

**Always remember:**

- Use clear and concise language throughout the SOP.
- A bulleted list of points can help make the SOP easier to read and understand.
- Where a process with multiple steps is being described in an SOP, it is good practice to develop a flowchart of each step to help readers visualise the process.
- Screenshots can also be used to illustrate a step-by-step guide to performing a process.
Cross-reference documents:

Ensure to cross-reference other applicable SOPs and working practices - whether on a global and/or local level. It is also important to cross-reference current guidelines and regulations appropriate to the content of the SOP.

Stakeholder input:

- The author must identify relevant stakeholders and who will have responsibility for the review and authorisation of the SOP on behalf of the company.
- A responsibility assignment matrix (RACI matrix) exercise will help define who completes the task(s) and who is accountable.
- The author should organise a meeting, either via skype or face-to-face, with the stakeholders to discuss the SOP and to go through the relevant sections that require input.
- The author should go through the SOP and allocate a section for the stakeholder(s) to review and to provide their input. The main stakeholders are to add any comments where they would want the document to be updated, or where they see issues or gaps in the SOP. The author will update the SOP taking those comments into consideration. Both the author and stakeholder(s) should agree a timeline for completion of the review.
- The author must closely monitor the review of the SOP in order to keep the cycle on track and provide regular prompts for feedback from the stakeholder(s).

How to manage the SOP cycle?

It is advisable that an SOP is reviewed every 2 years to ensure it remains up to date and in line with current procedures and working practices. The SOP should be updated upon:

- New or revised legislation that may affect the company’s processes.
- Adoption of a new business procedure by the company which affects the SOP.
- Changes in personnel and/or roles and responsibilities.
- Changes or updates in system requirements.

Overall Management of the SOP:

Many companies have made the transition from a paper-based system to a more automated and user-friendly system in order to close the inefficiencies paper-based SOPs can cause. Electronic systems are a more efficient way to locate documents, control version numbers, and to roll out the training to personnel to confirm that they have read and understood the information sent to them. The workflow is documented, and comments captured, the review process is date stamped and reports of personnel training can be run off at any time. But unfortunately for some companies, they do not have the luxury of having a digital platform to manage these crucial documents. This is where it is imperative that your naming conventions are consistent and clear. You could even develop an SOP checklist that details the SOP document name & number including names, signatures and dates of the author, reviewer and authoriser, changes made to the SOP and the effective date.

To summarise, remember the above guidance whilst managing the SOP cycle and ensure key company stakeholders are involved, because when it comes to performing a new task, the first document someone will turn to is the SOP.
Advance your career with Professional Training courses

PIPA offers its members peer-reviewed training courses, designed and led by industry experts, for professional development in Medical Information and Pharmacovigilance. These courses include assessments and validation and participants are awarded a certificate on completion of the course. With prices starting at £40 + VAT (online) and £350 + VAT (face to face), the courses are exceptionally good value.

New courses are currently in development and will be added to the training programme throughout the year.

For more details visit: https://www.pipaonline.org/Training/PIPA-Training-Programme

Online Training

- GVP Module I - Pharmacovigilance Systems and their Quality Systems
- GVP Module III - Pharmacovigilance Inspections
- GVP Module IV - Pharmacovigilance Audits
- GVP Module V - Risk Management Systems
- GVP Module VI - Management and Reporting of Adverse reactions
- GVP Module IX - Signal Management
- GVP Module XV - Safety Communication
- Introduction to Pharmacovigilance for non-Pharmacovigilance Personnel
- How to Facilitate a Successful Product Launch
- Data Protection - updated in line with the GDPR

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BREXIT AND THE QPPV, AN UPDATE

By John Barber

At the end of March 2017, the UK government triggered Article 50; effectively giving two years’ notice of its intention to leave the EU on 29 March 2019. The first wave of Brexit negotiations between the UK and the European Commission concluded at the end of 2017, with a transition period agreed to the end of 2020. The subsequent Withdrawal Agreement was not approved by the House of Commons and so Theresa May obtained an extension to the end of October (Halloween, appropriately) to get agreement on the deal to leave the EU. She subsequently resigned as Prime Minister, and was replaced by Boris Johnson. He stated that the UK will leave the EU on the 31st October, with or without a deal, “do or die”. It appears that die is the option as at the time of writing, a bill was approved by both Houses of Parliament to prevent the UK leaving without a deal at the end of October and to seek a further extension to the Article 50 notification. This is a rapidly developing situation and may be very different at the time of publication. As is well understood, post-Brexit, the EU QPPV must be based in an EU country. At the end of May 2017, the EMA stated that there were 1,358 registered EU QPPVs in the EEA, of which 153, 11%, were UK based (1). As of the beginning of September 2019, there has already been a decline in the number of UK-based EU QPPVs. Of a total of approximately 1,300 registered EU QPPVs, there are now only 119 (9%), based in the UK, a fall of over 20% (2). Of the 119 remaining UK-based EU QPPVs, some will be acting for UK-only MAHs and will not therefore have to relocate to an EU27 country or transfer their responsibilities. However, it is likely that a
significant number of the remaining UK-based EU QPPVs will be impacted and are either biding their time waiting to see how the Brexit negotiations develop, or are in the process of relocation/transfer of responsibilities to an EU27 country.

There was a small glimmer of hope that UK-based EEA QPPVs may have been able to assume the role of the deputy EEA QPPV. The EMA have stated that this is not acceptable and that the deputy must be established in the EU (3).

The MHRA has updated its guidance on the need for a UK QPPV post-Brexit (4). It notes:

- A UK QPPV should be established
- If at the point of Brexit, the MAH used an EU27 based EU QPPV, that person may assume the QPPV responsibilities for the UK until such a person is appointed. This temporary exemption applies for 21 months after the date of the UK leaving the EU. At time this guidance was first issued, this meant by the end of December 2020. It is not known if the 21 months exemption applies no matter what the eventual Brexit date is
- The UK QPPV should be notified to the MHRA via a Type 1AIN variation. This variation will also be used to update the summary of the pharmacovigilance system for each MA and to notify the UK PSMF number.

It is probably fair to say that we are still in a state of confusion. The EMA and MHRA are providing as much guidance as they can, and MAHs are implementing their Brexit plans. But these plans still have to consider multiple scenarios, from a hard no-deal Brexit, to possible revocation of Article 50. Unfortunately, we are dependent upon our political servants to help guide us through the next few months as the Brexit saga continues to develop and unravel.

References
1. Private communication. Email from EMA 22 May 2017
2. Private communication. Email from EMA 6 September 2019

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MEDICAL SYMPOSIA & THE ABPI CODE

By Rina Newton

Although medical symposia are a common activity for pharma companies to organise or support at learned society congresses, these may fall under several different categories of the ABPI Code (“Code”) and therefore affect the compliance criteria for each. This article discusses just a few areas that cause confusion, the associated compliance risks and ways to mitigate some of these.

“We can’t put prescribing information on as it’s a medical meeting.”

Many of the compliance risks associated with medical symposia stem from the fact that all meetings must be categorised under the Code and whilst medical departments may feel their meeting is not promotional, if it does not meet all the compliance criteria for a bona fide type of non-promotion, then it will always be considered to be promotional.

It is always tricky to navigate internal pressures and processes with respect to properly categorising a medical meeting as promotional, but the definition of promotion in the Code is clear:

‘any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale or supply of a medicine’

Furthermore, during their consideration of a PMCPA case relating to a BMS medical symposium, the Panel commented that “it was immaterial as to which department organised, reviewed, approved or funded the event; it was the content and arrangements which determined whether it was promotional”.

“This is genuine independent content.”

Many company-organised symposia tend to involve a selection of eminent speakers who may have national or international standing. A disclaimer to the effect that ‘the content of this meeting is independent and does not necessarily reflect the views of the company’ is meaningless when it comes to a company’s liability under the Code for the meeting content – both written and verbal.

When a speaker’s presentation at a Roche medical symposium breached the Code, the Panel noted that Roche “should have ensured that, irrespective of the speaker’s wishes, it had complied with the Code”.

AstraZeneca had a speaker contract in place which specifically mentioned that statements ‘must not cause offence either through the use of imagery or humour unbecoming the professional standing of the audience’ AND their speaker had been briefed in advance of the meeting. However, when the speaker referred to ‘sexygliptin’ (instead of saxagliptin) in an “attempt at humour” the company were still held liable for the resultant breach.

“Everyone else is presenting on unlicensed medicines.”

There are compliant medical symposia which allow for the proactive discussion of unlicensed medicines. For example, legitimate exchange of medical and scientific information (LEMS) symposia can take place for medicines that are under development (OR for licensed medicines where an indication is in development) - but there are many criteria that must be considered.

In a Janssen case, a medical meeting intended to be a LEMS symposia did not meet the criteria for LEMS and was deemed to be promotional. The Panel commented that one of the presentations included prescribing information (for the active comparator which was a licensed Janssen medicine) “so it appeared that there was a promotional element to the symposium”.

“We need to present data on our medicines to ensure this is genuine medical education.”

It is a common misconception that mentioning the whole class of medicines in some way negates the promotion of the company’s medicine and constitutes bona fide medical education or that the audience wanting to hear about it, makes it an acceptable activity.

The Panel noted that an Allergan activity promoted all botulinum toxins and so also promoted Allergan’s product Botox, “If this were not the case then the effect would be for companies to promote classes of medicines as a means of avoiding the restrictions in the Code.”
Whilst many companies cite “medical education” as the key intent of their symposia, this must be “information relating to human health or diseases provided there is no reference, either direct or indirect, to specific medicines”\(^6\). Any mention of a medicine in this context could be viewed as unacceptable promotion (or worse, pre-licence or off-label promotion).

“We only supported the symposia.”

When a company provides a grant towards a medical symposium under strict criteria and there is an arm’s length arrangement in place, the company is not held responsible for the symposia.

When a learned society conference session discussed an unlicensed use of PharmaMar’s licensed medicine, PharmaMar’s involvement in writing a Meeting Highlights document was not arm’s length. This meant the company was responsible for the document which, in effect, promoted the medicine for an unlicensed use.

**What are the solutions?**

A good starting point is to genuinely understand the intent of the meeting (vs impression) by asking “What are we trying to achieve? What do we need? What will the audience learn from this?”. This will help in deciding whether the meeting is promotional or not promotional.

Next is the proper categorisation of non-promotional meetings (“LEMS? Medical education?”) in order to find the compliance criteria to follow (company SOPs will contain such checklists).

If the checklist is well-adhered to, then this provides a good audit trail, not only to aid efficient approval but also to demonstrate Code compliance retrospectively.

If speakers and agencies are used, then due diligence, good contracts, written and verbal briefings will help ensure there are no issues during the meeting itself.

Remember you can’t find “medical symposia” in the Code, but case rulings and therefore learnings, can help us to navigate a compliant path forward.

**References**

1. Case AUTH/2781/7/15 - AbbVie v Bristol-Myers Squibb
2. Case AUTH/2598/4/13 - Consultant Rheumatologist v Roche
3. Case AUTH/2887/11/16 - Anonymous health professional v AstraZeneca
5. Case AUTH/UTH/2274/10/09 - Hospital Consultant v Allergan
6. ABPI Code of Practice 2019, Clause 1.2
7. Case AUTH/2979/9/17 - Anonymous, non-contactable complainant v PharmaMar

***Rina Newton***

Managing Director

CompliMed
HOW TO HAVE AN EFFECTIVE PERFORMANCE DEVELOPMENT REVIEW

By Christian Simon and Stuart Gregory

Rather than being a “one-off” meeting, the Personal Development Review (PDR) should be an important part of an ongoing process. Managers should have regular, high quality conversations with staff about their progress and what further development, support and advice is required to ensure they achieve their objectives and goals.

The formal PDR meeting, as an extension to this ongoing process, presents an opportunity to reflect on the past year and recognise achievements, challenges, development and progress. It is a time to make plans for the year ahead and set out objectives. A good review of performance enables both manager and employee to better identify the best way to approach personal and professional development over the next year.

Unfortunately, the process is often viewed with trepidation and as more of a “tick box” exercise. To encourage trust, it is important to present the meeting as a “two way street”. A good PDR should provide staff with the opportunity to feel valued and to open up and be honest. For managers, it provides the platform to gain valuable feedback on their own performance and how the employee views the organisation as a whole.

The following points in this article are aimed at making the process more productive and useful to both parties.

From a Manager’s Perspective:

- Use this as an opportunity to reflect on the performance of both the company and employee over the last 12 months, discussing any successes and setbacks.
- Highlight any positive impact their achievements have had on the team and overall business objectives, making them understand that what they do truly makes a difference.
- When discussing setbacks and professional challenges, give the employee a sense of shared ownership. Discuss potential training (internal or external), make them feel supported and that you are committed to working together to overcome these barriers to optimal performance.
- Discussing any useful and constructive feedback received from other colleagues can be useful if delivered in the right way. People want to feel liked and respected!
- Review the need to potentially update the employee’s job description. Has there been a significant change in responsibilities due to restructure or new projects? Is the company really valuing the total contribution from the employee?
- It might be that the employee is looking for a promotion or career change within the company. This is the perfect opportunity to discuss these goals and find out how best to achieve them.
- Take this opportunity to ask the employee if there is anything they want to discuss which is affecting them in their work and then offer any reasonable and appropriate support.
- Remember to ask open questions that can provide an indication of how you are performing as a manager. Ask them if they feel supported and what you or the business can do to help them further achieve the targets set.
- Ensure that action plans are aligned to team and company objectives and are SMART (specific, measurable, agreed, realistic/relevant and time-bound).

From an Employee’s Perspective:

- Approach your review with the mindset of enquiry and see it as an opportunity to learn and enhance your performance.
- The key to getting the most out of your review is preparation. Successful professionals will review their progress at intervals throughout the
Coming to the table with a well thought out and reasoned analysis makes you appear more focussed, committed and eager to learn.

- Ensure you take responsibility for your own development and discuss any self-learning you have taken on throughout the year. Ask to shadow others if appropriate and volunteer for additional duties. Discuss any training you identified which could be beneficial to your role. Your manager will also have some ideas but it pays to look proactive and serious about your own career.

- Share your preparations with management in advance if possible. This will help them prepare for your meeting more effectively and encourages a more meaningful two-way dialogue. It also helps them prepare for any differences in perception that might exist and avoids any surprises!

- Review your job description and the goals, competencies and development plans set out during your last appraisal. Use these to give you a real sense of your accomplishments, strengths and areas for development.

- Gather any reports that you created to monitor performance, such as project status reports. These will help you properly identify performance highlights, milestones and challenges.

- Think carefully before you respond and, if necessary, take time to check the validity of the feedback. In some instances, requesting a follow up meeting to address an issue is more appropriate.

- Listen with an open mind, accepting praise graciously and thanking your manager for raising points that can help you develop into a stronger, better-rounded professional.

- Set out a positive tone to the discussion by finding something in the content of the review you agree with and share your thoughts, insights and concerns in a constructive way.

- Be open and honest. Being positive for the sake of it doesn’t give your manager the opportunity to help you achieve your potential.

Finally, it is important to remember that there shouldn’t be any big surprises for either party during a Personal Development Review. If either is shocked by a revelation then that is a clear sign that neither have been speaking to each other often enough or honestly enough throughout the year.

As the famous self-improvement industry author Paul J Meyer once said - “Communication, the human connection – is the key to personal and career success!”

Please contact Christian Simon at christian.simon@axess.co.uk or Stuart Gregory at stuart.gregory@axess.co.uk for further information or any questions regarding this article and visit us at www.axess.co.uk.
HOW DO YOU RESPOND TO A PATIENT ENQUIRY?

Discussing PIPA’s newly published patient enquiries guidelines in the PIPA Live MI Webinar on 26th June

By Amy Doyle

How often do you receive an enquiry from a patient? What information do you think is appropriate to share with them? How do you interact with an expert patient? These are all questions that we face when dealing with enquiries from members of the public. During the PIPA Live MI Webinar on 26th June, the newly published patient enquiries guidelines, and the rationale behind them, were discussed.

Setting the scene

The webinar was an interactive one and started off with the poll question “How many enquiries do you receive from knowledgeable patients?” Most of us responded with 1-5 a week, while a few had a couple more or a couple less.

Gauging the level of scientific knowledge of the patient

While we know where we stand when responding to a healthcare professional, knowing how to respond to a patient can sometimes be difficult. One of the issues that we face with patients is assessing their level of knowledge and understanding of the subject in question. Thanks to Dr Google and the internet in general, many patients often have considerable understanding of their condition(s) and treatments. You may also receive enquiries from patients who are healthcare professionals or patients who have had the condition for so long that they have become expert patients.
PIPA’s guidance document includes a table with suggestions of how to gauge the level of scientific knowledge the patient has, and also incorporates a table which gives suggestions on the types of information that could be provided to the two different patient groups.

One of the sources mentioned in the guidelines, which expert patients could be referred to, is PubMed. When the question of referring patients to PubMed was put to the group, the majority voted on not sharing this resource. The reasons given included that even though they may be expert patients they are less likely to be familiar with how to perform a literature search, which in turn may not give them a balanced view of the literature and also unintentionally point them in the direction of off-label information. Therefore, if this source is to be used, it should be used with caution and potentially only mentioned during a verbal discussion, advising the patient that their search may not provide a clear and balanced result and they should always discuss their concerns and findings with their healthcare professional.

Structuring your response

Whatever the level of knowledge of the patient, PIPA have included in their guideline a template structure for written responses. It includes sample wording and suggestions on how to make the response more bespoke and ensure that we have understood the question, while clearly explaining the limitations of what information we can share and why these limitations exist.

Sometimes responses require only a short paragraph, which can then appear overwhelmed when all the additional disclaimers are included. For example, it is important to include an adverse event statement in our responses, but so as not to alarm the patient, it may be best to only use this statement in responses related to adverse events or suspected adverse events.

Peer-reviewing responses

The general consensus in the final discussion of the meeting, regarding the review of patient responses before being sent out, concluded that as per the PIPA Medical Information guidelines, most companies pass on written patient responses to a senior member of the team to review before being sent. However, in some cases, standard responses may be available, in which case they may not require peer review. On the other hand, where the information is more sensitive, this may require a review from a signatory. It really falls on the Medical Information individual to make the call and to liaise with their team when necessary.

Concluding thoughts

The interactive format of this webinar allowed the many MI teams to compare and share their experience and thoughts when dealing with patients. While certain resource material was disputed, such as PubMed, the overall consensus was that we all aim to provide informative and helpful responses to the patient while complying with the Code and our legal responsibilities.
PIPA LIVE PV WEBINAR
SUMMARY
18th June 2019
By Sian Casey

On 18th June 2019, Dora Amene and Tom Nichols hosted a PIPA LIVE PV webinar to discuss how PV can bring value to the business, patient education apps and the Medical Device Regulations. Dora and Tom were also joined by John Barber, Managing Director and Lead Consultant at Plain Pharma Consulting who very kindly gave an overview of the Falsified Medicines Directive and its implications for pharmacovigilance. A recording of the session, along with the slide decks can be found on the PIPA website at https://www.pipaonline.org/Login.aspx?ReturnUrl=%2fPIPA-LIVE---webinar-archive and for further information, or to suggest topics for discussion in future PV webinars, please contact us on pv-liaison@pipaonline.org.

Falsified Medicines Directive (FMD) and its implications for PV, John Barber

This session focussed on the FMD as the delegated regulation was published on 9th February 2016 with a required three-year implementation period before it became effective on 9th February 2019. The expectation was that from 9th February 2019 only FMD-compliant packs were to be released into the market after this date. However, whilst Marketing Authorisation Holders (MAH) and all stakeholders within the process were given three years to prepare, it became clear towards the end of 2018 that a lot of the stakeholders - including MAHs and retail pharmacies - were not ready for the implementation of the FMD. Following this, the MHRA has allowed some flexibility and for the implementation period to be extended to prevent disruptions to supply and, under certain circumstances, companies are still able to release non-FMD compliant products into the marketplace. In addition, there is some anecdotal evidence to suggest that some retail pharmacies have not yet installed the scanning equipment required for FMD as they believe that this may not be required in the event of a no-deal Brexit.

Key Features of FMD

1. Track and Trace: It allows medicines to be tracked and confirmed that they are genuine medicines, throughout the supply chain. However, this only applies to prescription-only medicines (POMs), with the exception of pharmacy omeprazole. This exception is due to a case in Germany several years ago where counterfeit pharmacy omeprazole was introduced into the supply chain.
2. Unique Serialisation Code: This code is a 2D data matrix and is unique to each pack and includes the batch number and expiry date information alongside other pieces of data. This is scannable at all stages of the supply chain for confirmation or decommissioning of the product.

3. Tamper Evident Device: Essentially, this is a strip that has to be broken to open the product packaging itself.

4. Alerts: There are five levels of alerts that can be issued when the product is scanned with level five being the highest alert, suggesting that it is a potential falsified medicine e.g. scan failed to find a batch number, expiry date doesn’t match the information stored in the data hub etc… If a level five alert occurs then all external stakeholders need to be notified and the system will send an automatic alert to the national data hub which will then go to the European data hub and from there to the MAHs and finally to the national competent authority. It is unknown at this time how this would be managed in the event of a no-deal Brexit scenario. In addition, the MHRA has requested that pharmacies report a level five alert via the yellow card scheme but the DMRC (Defective Medicines Report Centre) has confirmed that they will not investigate these reports - so how the MHRA will be involved in the investigation of potential falsified medicines is not currently clear.

Medical Device Regulations (MDR), Dora Amene

The EU established the MDR (Regulation (EU) 2017/745) and In Vitro Diagnostic Regulation (IVDR, Regulation (EU) 2017/746) to replace the Medical Devices Directive and In Vitro Diagnostic Devices Directive which had been in place for almost 25 years. These two new regulations were adopted by parliament on 5th April 2017 and the aim is to ensure the safety and effectiveness of the marketing of medical devices within the EU.

Key Differences between the Directives and Regulations

1. Scope and classification of medical devices: There have been several new rules regarding the classification of substance based devices which can be found in Articles 1(22/23) and (51/52).

2. Addition of the Unique Device Identification (UDI) system: This requirement is an example of where the EU brings EU devices regulations in line with regulations which are currently in place elsewhere in the world e.g. the US. The UDI places a unique code on the devices to enable the identification of potential counterfeit devices and the reporting of serious incidents.

3. Changes to Notified Bodies Supervisions and Responsibilities: Any notified bodies that would like to issue a CE mark certification now have to undergo a process of designation which involves the EC and medical device co-ordination group and the joint assessment team who will assess the application required for designation. However, the ultimate decision will sit with the individual member states. It is recommended that manufacturers contact their notified bodies regarding this as the change in process may cause some delays. Notified bodies are now also legally required to perform unannounced audits including audits on manufacturing sites, laboratory tests, suppliers and sub-contractors and these have to be completed once every five years.

4. Changes to Eudamed: Eudamed is the database for medical devices and is expected to go live in March 2020. This database will consist of other databases, including the UDI database and Vigilance database, along with clinical studies and performance studies data and will be accessible by competent authorities, notified bodies, industry and the general public.

5. Changes to Clinical Evaluation Processes: Clinical evaluation reports for Class 3 devices must be updated annually.

6. Role of Economic Operators: MDR has provided
guidelines to all stakeholders on how to implement these changes for assigned tasks and will serve as a way to enable all stakeholders to be able to complete their tasks effectively.

**Post-marketing surveillance (PMS) and Vigilance Requirements**

The MDR and IVDR have introduced new requirements for PMS and vigilance. This includes a Periodic Safety Summary Report to be prepared for medical devices which will summarise the results and conclusions of the PMS data and for the development of the Post-Market Clinical Follow-up (PMCF) and Performance Follow-Up (PMPF) processes that will update the clinical/performance evaluation data.

Both the MDR and IVDR were formally published on 25th May 2017. The MDR has a three-year transition period from the date of publication and the IVDR has a five-year transition period so the deadlines for the implementation of these directives are 26th May 2020 and 26th May 2022, respectively.

**PV bringing value to the business, Tom Nichols**

This topic was raised by a PIPA member who asked if there were any useful references or articles regarding PV bringing value to the overall business, raising the profile of PV and making it integral to a company’s strategy and future. A list of useful references can be found in the slide deck on the PIPA website.

Key areas that were identified that could showcase the value that PV brings to the business include opening up access to drugs for patients, a proactive approach to gain competitive advantages and help drive personalised healthcare for patients, being involved in early strategic involvement in key activities and commercial strategies and improving corporate image by highlighting patient centricity and showing how involved we are in driving patient safety.

**Patient Education Apps, Tom Nichols**

This topic was also raised by a PIPA member and they were interested in discussing the use of patient education apps and how much value they provided to patients.

There is a lot of innovation at the moment dedicated to driving information access to both HCPs and consumers including e-consent for clinical trials and medication tracking for patient compliance (e.g. diabetes medication tracking). The Research2Guidance report stated that the estimated number of users who downloaded mHealth apps was expected to reach 2.6 billion by 2020 with 551 million being active users, and the number of apps produced by pharma companies has more than tripled from 305 in 2013 to 988 in 2016. Health authorities are also producing and releasing apps and a good example of this would be the FDA releasing the MyStudies app to gather real-world data.

There are useful opportunities for apps that could be used to deliver information to patients. For example, a read and understand documentation app of risk minimisation activities could be a useful tool in driving patient engagement. However, considerations to ensure that the benefit is felt by those most in need should be taken into account e.g. patients that do not have a smartphone or who need additional support or guidance in being able to use the apps themselves.

**PIPA PV and MI Professional Awards and Training**

For more information regarding the PIPA PV and MI Professional awards please visit the PIPA website at [https://www.pipaonline.org/PIPA-Awards-2019](https://www.pipaonline.org/PIPA-Awards-2019) or email pipa@pipaonline.org and for more information regarding the training courses available face-to-face or online please visit [https://www.pipaonline.org/Training-1](https://www.pipaonline.org/Training-1) or email training@pipaonline.org.
THE PIPA WORKSTREAMS

As you may be aware, the PIPA Committee divides its work into 9 workstreams to allow it to function as an organisation and continually meet the needs of the membership. Each workstream is headed up by a Committee member. The workstreams vary in size, with some including PIPA members who don’t sit on the Committee itself.

We’ve ask the leads of each workstream to provide an overview of the work their team undertakes for PIPA.

**Code Compliance Workstream – Janine Gavin-Poulter**

Like many of our committee members within PIPA, I perform a dual role, the first as the Vice-President and the second as the workstream lead for Code Compliance.

PIPA has a joint venture with CompliMed where we provide our members access to a quarterly Code Forum to discuss recent case rulings by the PMCPA & MHRA, share best practices and experience and explore the impact legislations bring on Code-related activities.

My role as the workstream lead for Code Compliance is to raise current challenges faced within our organisations. What follows is a great interactive discussion where several other Code Forum attendees who have responsibility for Code Compliance within their roles as Medical Information, Medical Affairs or Drug Safety professionals, share similar issues and discuss practical solutions and ways of implementing these.

Following each Code Forum, I share a written summary of this information with the forum attendees and relevant committee members within PIPA so that they also have additional resources to assist in their daily roles. Relevant outcomes from the discussions may also be used to update PIPA’s guidance documents, if appropriate.

**Communications Workstream – Tom Nichols**

The PIPA Communications workstream is about how we communicate and converse with our membership. Across our eNews emails, website, LinkedIn company and group pages and Twitter (@PIPA_tweet) you can be sure to be kept up to date with the work being undertaken by PIPA’s working groups and training offerings, along with the most relevant industry updates.

This isn’t a one-way conversation though. Our LinkedIn group is a great place to share useful information with your peers and to look for advice on tricky situations you may be facing. If you prefer more anonymity, there are our MI and PV discussion forums on the website, which are regularly monitored by the committee and you can always contact us directly (via pipa@pipaonline.org).

Our free bi-monthly PV and MI PIPA Live webinars are an opportunity to speak directly with other members in an open forum. There are guest speakers delivering talks on hot topics and we encourage your questions and requests for discussion points.

The workstream would welcome any members with experience of, or a passion for, communications to ensure PIPA continues to effectively disseminate information and engage with the membership.

**Pharmacovigilance Compliance Workstream – Dora Amene**

As the PIPA PV compliance lead, I lead and coordinate all activities within the workstream - including the review, creation and updates of the PV standards and guidance documents for members, as well as helping to facilitate PV training and webinars.

The PV compliance workstream is supported by a working group of PV experts from different backgrounds (including consultants and company directors) with many years of experience - covering PV quality management systems, clinical and post-marketing PV, QPPVs and ex-ABPI PEN members – who come together to share ideas and knowledge that help drive the membership forward. The group meets quarterly to discuss topics of interest and address regulatory changes that require updates to the PIPA resources available to members.

**PIPELINE Workstream – Pooja Shah**

I joined the PIPA committee and PIPELINE workstream in 2015 and since then, this workstream has doubled in size. The workstream is currently split in two, with two committee members with a medical information background - Zeb Adomako-Mensah and Alena Attiyah - and two committee members with a pharmacovigilance background, Dora Amene and me. Between the four of us, we are in charge of ensuring our members receive three high quality journals over the year. Over the last four years, we have asked our membership to provide feedback on our PIPELINE journals and from that, we have tried to take on board what you would like to see more and less of, what is of interest to our members and what isn’t. We’ve tried to keep a balance between MI and PV articles, general QA feedback on audits...
and inspections and regular career development and progression features. Our aim is to ensure each journal is substantial, varied and topical to each of our members.

Our role on the workstream is to try to bring articles to you that are relevant and of interest and on topics that are pertinent and current, written by authors who have a wealth of experience and knowledge to share on the topic itself.

We try to encourage all our members to reach out to us via the email address journaleditor@pipaonline.org if you have any suggestions for articles you would like to see in the forthcoming editions of PIPELINE, or if you would like to volunteer to write an article for us. All four of us are available to help and support you if you choose to volunteer to write an article. We are always looking forward to hearing from our members so please do get in touch!

Medical Information Workstream – Tazneem Anwar

I joined the PIPA committee in November 2018. As the lead for the MI workstream, I co-ordinate all activities within the workstream. These include ensuring the development of resources for our face to face and online training courses, developing and running the content for the MI webinars, liaising and partnering with organisations such as UKMI and regularly feeding back to the Executive Committee on updates, progress and any issues. I hope to be able to work with the rest of the Committee to ensure PIPA continues to provide a platform to share best practice, raise standards and support personal development and training.

Training Working Party Workstream – Emma Boulton

I have served on the PIPA committee on and off since 2004 in various roles, and I currently co-lead the Training Working Party (TWP) with Esther, Bhav and Anne T. We work together to deliver both the online and face to face trainings for MI and PV using the skills of the members of the TWP.

Once each face to face training course has been delivered, we review the feedback from attendees and speakers alike to see what, if anything, needs to be changed. And that can be anything from facilities at the venue to advertising materials to course content. We then utilise these learnings when preparing for the next time the course is run.

For our online training courses, we ensure that when there are changes to regulations, code of practice etc., the content is reviewed and kept up to date.

We are always looking for new hot topics to either be incorporated into an existing training course or used to create a new offering. And on that note, we have several new online training courses for both MI and PV that we are currently working on, so keep your eyes peeled for news of these.

Conference Workstream – Anne Turnbull

Preparations for the PIPA conference begin the week after the previous conference has run, and our first step is to review the feedback from delegates who attended. We appreciate that filling in a feedback questionnaire is not most people’s top priority, but I cannot stress enough how valuable it is to help us understand what went well, and what we need to work on to improve for the next year’s conference.

Step two is to identify an appropriate venue for the next year’s conference and book in the dates – and to be honest, this is usually the most difficult aspect of conference organisation! We vary the location of conference to accommodate members based in different geographical locations, whilst working within a strict budget and venue size requirements. We try our very best to accommodate our members’ venue requests, but – as we are sure you appreciate – it is impossible to meet everyone’s requirements.

Once we have dates and a venue, step three is to brainstorm topics and speakers. Again, the conference feedback is invaluable for this, as members often have great ideas for future topics. The Committee also hold a number of brainstorming sessions to develop the programme, and we always welcome suggestions from our membership (via conference@pipaonline.org). We then approach potential speakers and begin to build the programme.

Alongside this, we look to invite companies to exhibit at conference. We are lucky that many of our exhibitors return year after year, but we also like to welcome new faces to showcase the wide range of skills and services available to our membership.

Finally, is the organisation of our evening meal and social event, which provides the perfect opportunity for delegates, speakers and exhibitors to network together in a fun setting. We try to choose entertainment that is interactive, inclusive and fun and in keeping with our venue. From murder mysteries to casino nights, circus skills, the wild west, magicians, 80s nights and quizzes, each year we have great fun brainstorming ideas for this popular event – but, again, we keep to a strict budget and try to ensure that it will be enjoyable for as many of our delegates as possible.

If you have any ideas for conference, then please contact us via conference@pipaonline.org.
BECOMING AN INDEPENDENT CONSULTANT

Lessons from the first 12 months

By Tom Nichols

In April 2018, I finally took the plunge and set myself up as a consultant and started my own company. Thankfully, almost 18 months later, I’m still in business. It’s a well-trodden path and I’m not exactly reinventing the wheel but, nonetheless, here are a few of the things I would recommend thinking about if you are considering the move yourself. These aren’t ‘five points to run a successful business’ or any sort of recipe for success, but they are things I’ve found valuable and have helped preserve my sanity.

Know Why

What are your reasons for foregoing the security of employment? Do you have a vision or a goal? I don’t mean a fluffy mission statement or the like (although, by all means go ahead!). That can be hammered home in your marketing material. It’s not possible to work in medical information (MI) and pharmacovigilance (PV) without caring for patient safety and ultimately wanting to make drugs safer, so we’ll take that as a given.

I mean, what is it that you will hold on to and keep you motivated when things might not be going well or help guide your decision making. For me, the ultimate goal is for Drive Phase PV to be a more full-service PV provider, which has informed decisions on the kinds of contracts I’ve taken and partnerships I’ve fostered. Now I’m in the midst of things, trying to achieve that goal, it is probably ego that that is the key why for now. I decided to do this and now I don’t want to fail. It’s probably not the healthiest of reasons but, hey, it works for me!

I don’t think it really matters whether the why is money, ego, variety of work, work-life balance or anything else. As long as it gives you the incentive you need to keep going, it’s good enough.

Use Your Downtime Productively

The first 6 months will be slow. Everyone will tell you and you won’t believe them. How difficult could it be to get a couple of contracts?! Once you’ve adjusted to initially not doing 40 hours paid work a week, and referred to point 1, make sure you keep yourself busy.

The first few months is the ideal time to set the foundations for the business, from designing the website to writing standard operating procedures (SOPs) and quality documents. You may not need them immediately and you may not finalise them, but even having the skeleton documents makes stepping up at a later date much easier. You don’t want to be frantically pulling together SOPs in response to agreeing to do some work, or an impending vendor-selection audit.

Don’t forget to maintain your professional training. Keep training records, read new guidance etc. There is no one spoon-feeding you now and you can’t afford to be left behind.

Being productive doesn’t have to mean all work though. One of the major advantages of consulting is the ability to reset your work-life balance. I’m sure I’ve wasted many a day to staring blankly at my monitor and reached 6pm without really achieving anything. However, any day I’ve taken away from the office to spend with my family and new baby is one I considered well spent.

Say “Yes”

While not completely in the Richard Branson camp (“If somebody offers you an amazing opportunity but you are not sure you can do it, say yes — then learn how to do it later!”), you do need to have the confidence to be able to deliver on things that may be new to you. If you’re in this for the long term, though, your reputation and future work will be more important than winning a single project you misrepresented your ability to succeed on. Knowing how to tread that line is important. Being open and honest about my set-up is important to me and while never having said no to an opportunity, I have laid out the risks
of using a newly set-up and expanding provider to clients. As long as you get things right in terms of point 4, below, then your credibility will only be enhanced.

**Understand What You Bring To The Table**

As with any job, know what you will bring to the client and why they should use you over anyone else, which will vary from client to client and project to project. For some it will be specific expertise to deliver a single project, others may want more general support and the comfort of you being able to turn your hand to most things. Really take the time to understand their needs and how your strengths play to that.

The first time I was directly asked why someone should use me over someone else, I suddenly realised I hadn’t thought it through properly and muttered something about being cheaper. Poor. I had failed to recognise that cost was inconsequential to them and what they wanted was the confidence and security that the project and associated business aims were to be met. No one ever got in trouble for hiring PPD or PrimeVigilance, so knocking a few quid off the bill was nowhere close to justification enough to sway any minds. There were myriad reasons I would have been a better choice and I managed to completely miss communicating any of them.

Every small company pushes themselves as ‘cost-effective’ but don’t just equate that with cheap and expect that to win any kind of work of value (either financially or intellectually). Remember, good value is not the same as low cost.

**Collaborate and Network**

Lots of projects are not possible for one person to deliver. DSURs will need to be quality checked, back-up provided in case of absences etc. Even if you eventually want to build a company with employees, in the early days you’ll most likely need to have a network of people and companies you can collaborate with and sub-contract to. These collaborations and the quality of work will be putting your reputation on the line, so you need to be hard nosed with using the right people.

Collaborating is also the easiest way to grow your client base as you immediately open up the potential for reciprocal collaboration when your partners need a gap in their services to be filled. No-one relishes cold approaching to drum up new business, so if you have a virtual network of collaborators then you know that even if you’re going through a period of not doing as much business development as you should, there’s always something going on elsewhere.

It’s also good to have people you know you can pick up the phone to, and have a matter with, if you’ve been beavering away solo for too long!

Consulting certainly isn’t for everyone and it took me a long time to build up the nerve to do it. I’d umm-ed and ahhh-ed for years and always thought if I did start something it would be in partnership with someone else. However, I pretty much did just wake up one morning and stopped finding the prospect of it scary so jumped on it while that mindset lasted. I fully acknowledge I was in a very fortunate position when starting up, with a supportive family and no financial concerns. Along with a risk averse approach of organic growth it meant that if Drive Phase failed the mortgage was still going to get paid and I’d be able to come away with little more than a bruised ego and a lifetime of my wife cashing in all the martyr points she’s accrued with her unwavering support. Hopefully it will never come to that…

“I knew that if I failed I wouldn’t regret that, but I knew the one thing I might regret is not trying.”  
- Jeff Bezos

Tom Nichols  
Director  
Drive Phase PV
As I write this report, it’s the beginning of summer and yet we are faced with mixed weather conditions and I am wondering whether we will enjoy a similar summer to last year. By the time this edition has landed on your desk, we will only be a matter of weeks away from PIPA’s annual conference in Stratford-upon-Avon, the birthplace of the famous playwright, William Shakespeare. In the home of great literary creativity, we bring incredibly well respected and creative people from the pharmacovigilance and medical information fields to speak at this year’s conference.

With an established agenda of high-profile speakers, I am hoping to see many of you at Stratford-upon-Avon on the 2nd & 3rd October. Due to the continuous good feedback we receive regarding Dr Sheuli Porkess, Dr Dave Lewis & Dr Rina Newton, I am delighted that all three speakers will be returning this year. We are also delighted to welcome back Mick Foy from the MHRA, who will be discussing the impact of Brexit on the pharmaceutical industry from the MHRA’s perspective.

The conference programme is brimming with a mix of pharmacovigilance and medical information breakout sessions, from PIPA’s very own Medical Information Workstream sharing best practices to Rebecca Godfrey helping us to build subject matter experts. We are welcoming back Dr Shelley Gandhi, who will be discussing the building of a pharmacovigilance system in light of changing legislations worldwide. PV expert, Jose Ortiz of PVpharm – who develops and delivers training for the EMA – will discuss EudraVigilance and EVDAS. Drive Phase PV’s Tom Nichols, a long serving and valued member of the PIPA Committee, will also be hosting a discussion on outsourcing and
the joint client-vendor pharmacovigilance system. The UKMi will be presenting the findings from the recent UKMi survey of Pharma MI teams, and Ranjana Khanna of Vifor Pharma will be exploring the hot topic of inspection readiness from an MI perspective.

And, of course, there’s our evening entertainment and networking event to look forward to. This is always a great way to meet colleagues in similar roles in other organisations in an informal — and fun - setting. Finally, we mustn’t forget our exhibitors — a select group of companies who provide products and services relevant to your roles, without whom conference would not happen!

For further information regarding the conference programme and how to book, please go to: http://www.pipaonline.org/Conference-2019

Finally, this year we are introducing the PIPA Professional Awards to recognise the outstanding achievements and demonstrated excellence of pharmacovigilance and medical information professionals within the industry. So please do take a moment to nominate a colleague you feel performs their role with great strength and accountability by going to: https://www.pipaonline.org/PIPA-Awards-2019 and filling in the Awards Entry Form; you will be glad you did and, more importantly, so will your nominated colleague.

PIPA’s Training Working Party has been busy running webinars and face-to-face courses and yet somehow they have still found the time, with their immensely busy workloads, to develop new courses. We are delighted to launch a new face-to-face course which has been developed for pharmacovigilance personnel responsible for the management of affiliates - aptly titled “Affiliate Management in Pharmacovigilance”. This course is now available for booking via https://www.pipaonline.org/NEW-Affiliate-Management-in-Pharmacovigilance. This course was created due to a highlighted gap by one of our PIPA members and as such, we encourage all of our members to reach out to raise an unidentified training need; please contact us via training@pipaonline.org should you wish to discuss any training requirements.

And finally, dare I say it, the B word, Brexit. Over the last three years, Brexit has played a monumental part in our workplaces. With the 29th March deadline long gone, I write this article whilst we are heading for a new exit day of 31st October, with our country’s leadership still under question. It’s no wonder the pharma industry still has questions as it hopes that a pragmatic approach will be taken when considering patient needs. We have had changes to marketing authorisations, clinical trials, EU QPPVs with the introduction of UK QPPVs, changes in the site of QC testing and QP certification and let’s not forget, the relocation of the EMA.

Change is something we are used to in the pharma industry yet uncertainty in this situation makes us all a little anxious. Nevertheless, the last part of the year is all about recognising your own achievements and how you overcame any obstacles to them. It is important to continue to embrace and adapt to new challenges whether it be professionally or personally and, most importantly, keep smiling!

I hope you have enjoyed reading this edition of PIPELINE and I look forward to meeting some of you at this year’s conference. Please come by and say hello.
Who are we?
The PIPA committee is the backbone of the association; and this page features all the current contact details. The Committee is supported by 3 part-time contractors, whose details are also included on this page.

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