Ashfield Healthcare Communications Highlights from European Meeting of ISMPP 2019

Scientific Communications in a Fast-Paced World: Fighting Fit for the Future
The Ashfield Healthcare Communications team attended the European meeting of ISMPP this January. The two days were packed with a range of topics centred around Scientific Communications in a Fast-Paced World: Fighting Fit for the Future. The following paper delves into some of the themes discussed at sessions and round tables.

**Overview**

Following a welcome to the event and a look back at 2018, delegates heard a discussion on the power of evidence in a data-led future, followed by a keynote speech from David Sweeney of Research England. He discussed the hot issue of Plan S and what it means for scholarly publishing. Delegates then participated in roundtable sessions on current topics such as GDPR, the practical challenges of authorship, and publishing on specialist areas. The day rounded off with a session on the expanding role of the publication professional.

**Day 1**

Following a welcome to the event and a look back at 2018, delegates heard a discussion on the power of evidence in a data-led future, followed by a keynote speech from David Sweeney of Research England. He discussed the hot issue of Plan S and what it means for scholarly publishing. Delegates then participated in roundtable sessions on current topics such as GDPR, the practical challenges of authorship, and publishing on specialist areas. The day rounded off with a session on the expanding role of the publication professional.

**Day 2**

The second day opened with parallel sessions on topics including leveraging medical data and innovations in data publishing, followed by a talk on the role of leadership in driving publication integrity. Keynote speaker Simon Fry, Digital Product Development Director at Springer Healthcare, then gave an insightful talk on Artificial Intelligence (AI) entitled ‘No More RoboWars’ during day 2 of the meeting. Simon has more than 15 years’ experience in the digital arena, including roles as a programmer and website developer. Referring to the “amazing space we find ourselves in”, Simon spoke about the evolution of AI and provided fascinating insights into the current and potential future role of AI in science and technology, avoiding a lot of the jargon that is rife within the digital space.

**Artificial Intelligence**

Simon Fry, Digital Product Development Director at Springer Healthcare, delivered an enlightening and thought-provoking keynote presentation on Artificial Intelligence (AI) entitled ‘No More RoboWars’ during day 2 of the meeting. Simon has more than 15 years’ experience in the digital arena, including roles as a programmer and website developer. Referring to the “amazing space we find ourselves in”, Simon spoke about the evolution of AI and provided fascinating insights into the current and potential future role of AI in science and technology, avoiding a lot of the jargon that is rife within the digital space.

**Evolution of AI**

Looking back at the evolution of AI over more than five decades, Simon talked about the initial sound theory of AI, including the development of algorithms and mathematical models, and the building of neural networks. During the next 30 years, AI development was slow (“the AI winter”) because available computer power was insufficient and the huge amount of data needed to fuel AI was unavailable. A dramatic upsurge in the development of AI technology ensued, with problems relating to the previous scarcity of data resolved by big cloud providers, such as Google.

**Where are we now?**

We are currently in the era of narrow AI. This form of AI is focused on performing a single task, such as spam filtering, language translation, speech recognition, face recognition, playing chess or Go (see table, pg 4). This is the only type of AI used widely today and it has many real-world applications; examples include automation of routine jobs; identification of patterns of data in the medical setting; and research support. By contrast, general AI, which remains elusive, involves thinking, understanding and problem solving, without close direction by humans.
Key milestones in the development of narrow AI technologies, with widely reported practical applications, are presented in the table below. Focusing on clinical scenarios, Simon described how recent advances in AI technology are assisting radiologists in the quantitative analysis of images (InnerEye; Microsoft) and clinicians in the delivery of personalised medicine (IBM Watson). He presented an interesting overview of Synchrogenix, which uses natural language processing and recommunication of information from the trial protocol and statistical analysis plan to produce basic study reports. Skilled medical writers provide further content development and intellectual input into the reports.

Examples of narrow AI technologies have developed over the last 20+ years

<table>
<thead>
<tr>
<th><strong>Deep Blue, 1997</strong> (IBM)</th>
<th>Chess expert system (trained AI): the first system to win a chess match against a world champion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AlphaGo 2016</strong> (DeepMind®)</td>
<td>Developed by DeepMind. Different level of capability: beat the world Go champion by following the rules</td>
</tr>
<tr>
<td><strong>AlphaGo Zero 2017</strong> (DeepMind®)</td>
<td>Improved on the above</td>
</tr>
<tr>
<td><strong>AlphaZero 2018</strong> (DeepMind®)</td>
<td>Improved on the above, beat Stockfish, a highly successful chess algorithm</td>
</tr>
<tr>
<td><strong>Project InnerEye</strong> (Microsoft) [<a href="https://www.microsoft.com/en-us/research/project/medical-image-analysis/">https://www.microsoft.com/en-us/research/project/medical-image-analysis/</a>]</td>
<td>Supporting clinicians through medical machine-learning technology; innovative tools for the automatic, quantitative analysis of three-dimensional radiological images</td>
</tr>
<tr>
<td><strong>IBM Watson</strong> [<a href="https://www.ibm.com/watson/">https://www.ibm.com/watson/</a>]</td>
<td>Partnership between Sloan Kettering Hospital and IBM Watson. Used to interpret huge volumes of patient data and reduce to critical decision points. Improves the ability of clinicians to deliver effective treatments, and helps to personalise therapy</td>
</tr>
<tr>
<td><strong>Synchrogenix</strong> [<a href="https://www.synchrogenix.com/">https://www.synchrogenix.com/</a>]</td>
<td>Consultancy of regulatory and medical writers in the industry, using machine learning and AI to generate regulatory submissions</td>
</tr>
</tbody>
</table>

What does the future hold?

Business professionals and consultants, astrophysicists, neuroscientists, economists and computer scientists are among current trailblazers in the AI field. There is a broad spectrum of viewpoints and speculation about AI and its role in the future, particularly in regard to general AI, including extreme claims that it will lead to AI singularity, the theory that the development of an artificial superintelligence will lead to changes in human civilisation.

While some experts have expressed concerns about narrow AI assisting and augmenting certain routine jobs, with an inevitable change in patterns of work and job losses, others support the notion that automation will lead to new, more interesting jobs (e.g. managing computer software), together with economic benefits. Simon noted that rapid developments in AI technologies and their deployment would lead to a new “ecology of jobs”. When considered as cheap prediction, AI brings with it incentives to capture more data for use in prediction tools that assist in decision-making and lead to better prescribing. Importantly, advances in AI must be considered in the context of legal, emotional, socioeconomic and financial implications.

“Amazing space we find ourselves in”

Concluding the presentation, Simon said that with the widespread use of narrow AI in the future, the value of things that cannot be automated, most notably human-to-human interaction, will become increasingly highly valued.

a Core targets for DeepMind are the advancement of science, drug discovery and novel treatment strategies.
Real-World Evidence

The importance and influence of real-world data (RWD) and real-world evidence (RWE) in healthcare has grown rapidly over recent years. Keith Evans (Springer Healthcare) provided an overview of RWD/RWE during his presentation in the session “Harnessing the power of evidence in a data-led future” on day 1 of the ISMPP meeting. Matt Booth and Richard Macaulay (Parexel) discussed RWE and its role in support of the reimbursement of medicines during the “Early rise evidence boot camp” parallel track session on day 2.

RWE, evidence gathered through interpretation of RWD, provides regulatory support for drugs in the pre-development phase, the market access phase, and market usage phase. Today, developers of new medicines use RWE insights when designing clinical trials, including the inclusion of outcome endpoints relevant to patients. RWD is easy to gather using new digital technologies.

Examples of the main sources of RWD

- Pragmatic clinical trials
- Prospective observational studies
- Electronic health records/medical chart reviews
- Electronic medical records
- Administrative claims and billing databases
- Disease, product and patient registries
- Patient-generated sources e.g. patient surveys
- Health surveys
- Mobile phones and health-related apps
- Social media

For more than 50 years, randomised, controlled trials (RCTs) have been accepted as the ‘gold standard’ in terms of best evidence on efficacy. Historically, RWE was largely overlooked due to concerns among the scientific community that observational RWE from clinical practice could be misleading. Over time, with the exponential growth of the digital space and the availability of vast amounts of data, RWE has gained traction and now has an important place in healthcare decision-making. Importantly, RWE provides information beyond that which is available from a clinical trial alone, thereby extending our understanding of the effectiveness of a medicine. It has many applications, including the provision of clinical evidence for evaluation in the development of clinical guidelines and in healthcare decision-making. Additionally, it has a valuable role in providing information on disease burden, such as epidemiology and treatment patterns, and is used to identify situations where there is an unmet need for research, including clinical evaluation of established or new drugs. However, RWD has a number of weaknesses, such as potential problems with data quality, the influence of bias, and issues around reliability if not collected correctly. Custodianship, data protection and privacy are of paramount importance.

Over time and with continued communication and dissemination of knowledge about RWE, it is likely that there will be a growing confidence among healthcare stakeholders in the value of RWE. Through diligent data analysis and interpretation, it is inevitable that RWE will be used to help inform healthcare decision-making and improve access to medicines around the world.

Plan S - Making full and immediate open access to research publications a reality

In the first of two keynote sessions at ISMPP EU 2019, Dr. David Sweeney (Executive Chair, Research England) and Dr. Claire Moulton (Publisher, The Company of Biologists) discussed the aims of, practicalities and concerns with the implementation of Plan S.

Dr Sweeney highlighted that a substantial amount of scientific research is being withheld from the scientific community and society as a whole, due to the existence of publication paywalls. In the interests of making research more accessible and advancing, not hindering science, these barriers should be removed. Plan S, an initiative of cOAlition S, a group of national research funding organisations supported by the European Commission and the European Research Council, requires that from 1 January 2020, scientific publications reporting research funded by public grants must be published in compliant open access (OA) journals or platforms.

Key goals of Plan S:
- Achieve a system of scholarly publications that is more transparent, efficient and fair
- Promote a shift towards new models of academic publishing
- Foster a culture that ensures all scholars, and in particular early career researchers, have the opportunity to excel and advance their careers

Three roads to compliance with Plan S

<table>
<thead>
<tr>
<th>Publication in OA journals or OA platforms</th>
<th>Deposition of scholarly articles in OA repositories without embargo</th>
<th>Hybrid journals under transformative agreements</th>
</tr>
</thead>
<tbody>
<tr>
<td>• DOAJ registered</td>
<td>• Immediately upon publication, version of record or author’s accepted manuscript deposited in compliant repository; available immediately OA (no embargo) under CC-BY licence</td>
<td>• Journal committed to a full OA transition</td>
</tr>
<tr>
<td>• Journals must comply with industry standards (e.g. COPE)</td>
<td>• Support for DORA</td>
<td>• Collaborate with ESAC to register contracts</td>
</tr>
<tr>
<td>• Support for DORA</td>
<td>• CC-BY 4.0 licence required by default; rights retained by author/institution</td>
<td></td>
</tr>
<tr>
<td>• CC-BY 4.0 licence required by default; rights retained by author/institution</td>
<td>• OpenDOAR registered</td>
<td></td>
</tr>
</tbody>
</table>

For more than 50 years, randomised, controlled trials (RCTs) have been accepted as the ‘gold standard’ in terms of best evidence on efficacy.
Plain Language Summaries

Motivated in part by the EU mandate (EU Clinical Trials Regulation 536/2014 Article 37) that all new clinical trials must have a lay summary, Plain Language Summaries (PLS) are becoming an increasingly popular item to broaden the reach of medical information. cOAlition S’s roundtable option of PLS was fully attended for both sessions, indicating rising interest.

The basic premise of a PLS is that it covers the information in the item being summarised with:

- A suggested reading level of 12 years old;
- No additional material out of scope;
- An option to use infographics/visual elements.

PLS can be broadly split into two types:
1. Those requested by a third party (eg, journal), which will then have specific limits and audiences, and may be peer-reviewed; and
2. Those commissioned within the pharma company for one-off use, eg on a company website or for distribution at a specific congress, for which the specifications will be set internally.

Option 1 - will come with clear specifications, so these should follow the usual writing procedures, but with additional review by a non-scientist, and Legal may also need to approve the principle and process for this type of publication. It is also worth considering:
- if an agency is usually used for writing, consider using them for this writing task too, as this will assist with transparency of development;
- there are programmes and apps to assist with language levels, eg the Gunning Fog Index
- if the pharma company/agency has writers specialising in patient information, use them;
- if study is in partnership, partner Legal may need to sign off too

Option 2 - has additional considerations:

Who is the intended, and the possible, audience?
- Any visitors to a pharma website, which may include journalists
- Trial participants

Check early on if to be branded or not branded
- If study is in partnership, partner Legal may need to sign off too

Consider what links/references might be added for further information

What is the expected lifetime of the PLS
- Might a ‘use by’ date be useful, to indicate when the content might be superseded?

Assessing the success of PLS will vary according to point of release: PLS at congresses, if accessed via a QR code or similar, might be tracked by downloads, time spent browsing; hard copies can only be tracked by number distributed. There is anecdotal evidence of successful reach, but this cannot be quantified unless there is an associated questionnaire or similar option, which might cover several features of the congress.

Key points
- No additional data!
- Identify type, length and format – infographics aid easy understanding
- Have legal sign off on the principle as early as possible

Dr Sweeney acknowledged that there had been some difficult conversations around Plan S. Among the major knee-jerk reactions of stakeholders to Plan S are the potential impact on authors’ free will to choose where they wish to publish their results, the timeline for implementation, publisher concerns over hybrid journals not being deemed compliant with Plan S and the impact of Plan S on their business models.

Hybrid journals and mirror journals are not compliant with Plan S (unless they are part of a transformative agreement), the issue being that they charge for both access and publication – so-called “double-dipping”. There clearly needs to be a valid, sustainable business model in place for publishers to flip over to fully Gold OA; at the end of the day, their revenue comes from subscriptions and article processing charges. cOAlition S acknowledges that different models exist for financing and paying for OA publication and is calling for full transparency and monitoring of OA publication costs and fees. Publishers are worried though; notably, during discussions at one of the OA roundtable sessions at ISMPP, publishers noted that a complete switch-over to fully OA would result in a proportion of journals and their associated societies going bankrupt – “it would kill off part of the market”.

Providing the viewpoint on behalf of non-profit community journals, Claire Moulton elaborated on concerns around the timescale of Plan S and the proposed ban on hybrid journals. Dr Moulton explained that many believe that the hybrid model is transitional, and that the observed plateau effect in the uptake of OA content in hybrid journals is in fact a result of funders not supporting an “author pays” model – if journals are to flip over to fully OA, the majority of relevant funders would need to support article processing charges (or a suitable alternative). There needs to be a way to transform some of these areas outside of the timeline specified by Plan S. Dr Moulton called for funders and publishers to think carefully about the details of Plan S, particularly quality and transparency aspects, and how these apply directly and indirectly in the research and publishing cycle.

Clearly, there are a number of issues to be resolved in order to get the wider scientific community on board with Plan S. In the period from November 2018 to 8 February 2019, cOAlition S are welcoming feedback on Plan S, with a view to releasing an updated guidance document in the spring.

“It would kill off part of the market”
Blockchain for Publishing

In its most basic form, blockchain is a list of records (blocks) that grows, linked by cryptography, with a cryptohash of the previous block, and a timestamp and transaction data, which is saved across a peer-to-peer distributed network, with a copy of the blocks kept on every node of the network. The key feature of blockchain is that a change to one block makes changes to all the blocks. The value of blockchain is as a source of decentralised information (distributed ledgers) that is secure and practically incorruptible.

Most of us are familiar (without, perhaps, any deep understanding) with the concept of blockchain in relation to bitcoin. More recently it has been used as a form of music distribution, whereby the musicians receive payment direct for their creations; and it is in commercial use for supply chain monitoring. It has also recently been used for holding healthcare records for refugees. And now, it has the potential to be applied to scientific publishing.

Blockchain is not ‘owned’ or controlled by a single entity: this also means that there is no restriction on the data by entities owning the process of production. This is much of its appeal for fiction publishing; but how does it compete against the current scientific/academic publishing landscape of articles in peer-reviewed journals? Blockchain should be viewed as a host function – it would play no part in the validation of the data/peer-reviewing. It does have a potentially game-changing role to play in sourcing data from multiple sources (CSRs; patient records; published data) and feeding into the whole ‘big data’ scenario that could yet change healthcare.

Combined with the use of preprint archives (e.g. arXiv; bioRxiv); and open-review platforms (e.g. F1000; DEIP), this could move science on from what some see as the monopoly held by scientific journals, and their undue influence on research areas, and careers.

As with anything that is a radical change to the current process, there are PROs and CONs.

**PROs**
- This could be a rare opportunity to adopt best features of openness and sharing.
- ‘Peer review’ might become ‘establishment of consensus’.
- Blockchain ‘publishing’ could link up with healthcare systems, EMRs (with patient permission), and rapidly enhance real-world data, trends and patterns.
- Blockchain is here to stay: the industry needs to adapt or die.

**CONs**
- We are probably on the first upswing the Gartner hype cycle for blockchain: some disappointment is bound to follow before equilibrium is reached.
- Growth of blockchain might increase the risk of centralisation as need for (expensive) processing power might consolidate data across fewer networks.
- The publishing industry has a vested interest in the status quo (and governments have a vested interest in the revenue from established industries).
- ‘Publish or perish’: who is prepared/can afford to test the waters?

Closing Summary

We live in a fast-paced world and are continually subjected to ‘information overload’. We, as publication professionals, need to adapt and innovate by harnessing the power of the available and emerging technologies in order to communicate effectively and bring value to all stakeholders.

To maximise the value/impact of publications, data needs to be put into context and made meaningful. Research must be packaged and delivered in a useable form. We need to consider how different end users consume content and deliver appropriately, pitching at the right level and providing information in an easily digestible format. In this age of social media and fake news, where there is a real potential for information to be altered/misconstrued, we must continue to uphold standards and work with integrity to produce high quality communications that get the right messages across.

2019 EU Meeting Demographics
Attendees by country

<table>
<thead>
<tr>
<th>Country</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom</td>
<td>206</td>
</tr>
<tr>
<td>United States</td>
<td>16</td>
</tr>
</tbody>
</table>

Source: the fact above is from a live poll conducted during an ISMPP session.
For more information

Authors
Cate Foster, Publications Manager
Emma Landers, Principal Medical Writer
Caroline Perry, Scientific Director

If you would like to speak to us about how Ashfield Healthcare Communications could work with your business please email:

newbusiness@ashfieldhealthcare.com
www.ashfieldhealthcare.com