HIGHLIGHTS FROM THE JOINT MEDICAL AFFAIRS SUMMIT 2022

The APPA-MAPS Joint Medical Affairs Summit 2022 was held in Sydney from 17 November to 18 November 2022, bringing together over 200 Australian medical affairs professionals. The program included thought-provoking plenary and keynote presentations, a panel discussion on the MAPS 2030 White Paper as well as engaging workshops throughout both days.

APPA to MAPA

Matt Britland, President of APPA, announced the rebranding of APPA to the Medical Affairs Professionals of Australasia – or MAPA for short – at the APPA-MAPS Joint Medical Affairs Summit 2022. 'APPA and MAPS want to drive medical affairs forward into a profession. We want students to go to university and study to become medical advisors; we want to develop pathways to make that happen. We also want to have standards in Australia...,' Matt explained, '...the medical and scientific part of APPA is prehistoric; it doesn't matter what your background is — we are all medical professionals... we wanted to do this to represent medical affairs and the way it's changed'. Matt further explained, 'We really want to master these four pillars of medical affairs, advocacy, professional development and we also want to develop a capability framework'. Please note that all current APPA memberships have now been transitioned to a MAPA membership.


Matt Britland, President of MAPA

> "Our vision is that we want everyone in Australia who is in medical affairs to recognise that we are the peak body in Australasia."
>
> Matt Britland, President of MAPA

Keynote presentation:

Space medicine – an out of this world approach towards drug development

Presented by:

Dr Joshua Chou,
School of Biomedical Engineering/ FEIT, University of Technology Sydney

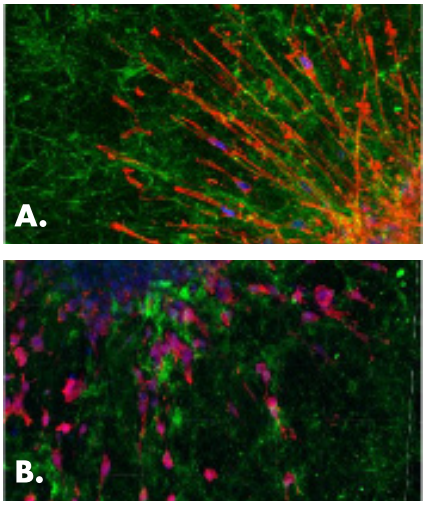
Dr Joshua Chou provided an exciting overview of the use and potential of space medicine to transform and revolutionise drug development. Dr Chou began by highlighting how research in space medicine, specifically research conducted in microgravity, can lead to better clinical outcomes for patients.

Dr Chou's first example focused on osteoporosis and how space medicine aided in the development of an anti-osteoporotic treatment. The human body experiences rapid change under microgravity, particularly in bone structure and density. Weakening of bones is common for astronauts while in space due to microgravity, with some astronauts noticing pronounced effects on strength upon returning to earth; osteoporosis shares similarities to this phenomenon. Dr Chou detailed how microgravity was used to simulate osteoporosis in animal models and how this clinical research performed on the International Space Station (ISS) led to the eventual development of the anti-osteoporotic drug EVENITY® (romosozumab-aqqg).

Dr Chou described how microgravity can help accelerate drug development and our understanding of human biology, posing the question, 'How do we uncover and unravel those mechanisms so that we can apply technologies, like artificial intelligence (AI), to accelerate these developments?' Dr Chou explained how he and his team investigated a cancer model under microgravity, and how developing this model could play a role in drug development. Cancer, like bone, is highly mechanosensitive, meaning that it is susceptible to mechanical stimulation. It was demonstrated that breast cancer cells in microgravity change their shape rapidly, thus changing their function and their ability to proliferate and migrate.

> "I think the next big thing in space medicine will really be accelerating that disease model and also identifying or repurposing existing drugs."

His team undertook a high throughput screening of 4,000 drugs and found that seven drugs — despite not being designed for breast cancer — were effective against these cells under microgravity conditions, demonstrating that changes in the function of cancer cells under microgravity can alter the efficacy of drugs.



A) Glioblastoma under normal gravity conditions.
B) Glioblastoma in microgravity.

Dr Chou also discussed how his team investigated glioblastomas by constructing a model of the blood brain barrier (BBB) using microgravity. Glioblastomas are difficult to treat due to the limited permeability of the BBB, making it difficult for drugs to access the brain. His team demonstrated that the permeability of the BBB increased after exposure to microgravity, allowing drugs targeting glioblastomas to enter the brain. Dr Chou stated, 'If we can control to a certain degree how it [BBB] opens and when to close it, then it means we can complement it with therapeutic treatments as well'.

Dr Chou ended his presentation by discussing the potential industrial applications of microgravity, specifically biomanufacturing, biofabrication, and the future development of space medicine.

workshop:

A practical guide to elevating the patient voice

Presented by:

Brittany Schoeninger – Principal, Real-world evidence, IQVIA
Jan Lewis – Associate Medical Director, AbbVie; APPA Executive Committee
Krystal Barter – Founder of Humanise Health Australia

Brittany Schoeninger, Jan Lewis and Krystal Barter led a thought-provoking workshop about the importance of elevating the patient voice in decision-making and how medical affairs can enable this.
The first section of the workshop discussed the current challenges in medical affairs that prevent industry from engaging patients. A recurring message regarding person centricity has been that early and effective patient engagement is critical, and patients must have a say in decision making. This topic has garnered the attention of various stakeholders across the healthcare system and is reflected in recent policy documents and reports in Australia and abroad. However, there is currently a lack of common language between healthcare professionals and patients that could enable real, effective dialogue, resulting in decision makers lacking important contextual knowledge and not understanding outcomes that are important to patients.
The second section of the workshop involved tackling the perceived and actual challenges preventing patient engagement with respect to the Medicines Australia (MA) Code of Conduct. It was concluded that the MA Code does support industry and patient collaboration, so long as companies engage patients with the objective of enhancing the quality use of medicines and supporting better health outcomes.
The final part of the session explored practical solutions to engage patients effectively. Some practical tips included involving patients early in study design and planning, implementing mechanisms to increase access, participation and representation as well as engaging advocacy groups to support recruitment through alternative channels.

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workshop:

ANZ industry standards for medical on-boarding

Presented by:

Robin England – Head of Medical Excellence ANZ & International Medical Excellence Lead, AstraZeneca
Riaz Abbas – Global Learning & Performance Lead, Amgen

Robin England and Riaz Abbas moderated a highly interactive workshop that challenged the participants to reflect and comment on current standards in medical affairs and to imagine what the future might look like.
It became evident that on-boarding of new personnel varies across organisations. Global resources can be useful, but the learning experience needs to be personalised and reflective of individual learning styles and preferences; in this respect, a model of co-creation of learning content would be an advantage. Future activities could involve the use of an artificial intelligence (AI) tool for a more tailored learning experience; however, face-to-face consolidation and peer interactions are still highly valued and necessary. As a solution, a buddy system or wider community 'hugs' group can be useful. For individuals that are new to the industry, an 'internship' model would greatly assist in the understanding and relevance of the wider functional teams within the local organisation.

Jan Lewis, Brittany Schoeninger and Krystal Barter

workshop:

Bench to Bedside: Evolving role of medical affairs in early drug development

Presented by:

Arvinjit Singh – Senior Medical Manager, AbbVie
Catherine Coleman – Pipeline MSL, AbbVie
Rosanda Kovacevic – Clinical Operations Manager, AbbVie

Arvinjit Singh opened the session with a summary of the current and traditional activities of medical affairs personnel. This was followed by an insightful overview by Jan Lewis regarding study and data delivery and how medical affairs at a local level can benefit through working effectively with global research and development to identify and evaluate sites for global registration studies. The benefits of this early engagement with key medical experts were elaborated upon by Catherine Colemen who shared her own experiences as a pipeline medical science liaison involved in early phase drug development. Such collaborations can drive insight generation that can influence scientific education and communication strategies. Furthermore, early involvement in the clinical development program can assist with understanding the burden of disease and the patient journey.

The final session involved a highly engaging workshop whereby delegates were divided into groups and asked to report on several features relating to various scenarios, including a planned site initiation visit and a poor performing centre.

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workshop:

Shaping the future of medical affairs by rebooting communication and engagement

Presented by:

Dr Tamara Etto – Head of Medical Affairs APAC, Antengene; APPA Executive Committee
Annree Wogan – Co-Founder and Principal Consultant Garrolagh Consulting & Pharmaceutical Development Australia

Dr Tamara Etto and Annree Wogan

Run by Dr Tamara Etto and Annree Wogan, this intriguing workshop provided insights into effective communication and how medical affairs teams can improve their communication skills. The first session focused on decoding communication, specifically, decoding the five 'Cs' of communication: Clarify, Collaborate, Critique, Care and Celebrate. Most people find only two of the five communication codes easy, while the remaining communication codes must be consciously improved. Participants were asked to rank their five 'Cs' from strongest to weakest and discuss their results with other participants. The second session focused on active listening. Attendees were asked to rank their competency as an active listener and discuss these results with their group. The final session focused on 'Push and Pull' behaviours. Push behaviours are defined as giving views and opinions, stating needs and wants and supporting/challenging ideas; Pull behaviours are defined as active listening, drawing out views and opinions and building common ground. These skill sets are core competencies that can be developed and improved. Participants were asked to take a Push/Pull assessment, selecting green if it is a natural skill, yellow if it is not but are consciously competent, and red if it is not natural and they spend time feeling consciously incompetent. It was noted that there needs to be a balance between 'Push and Pull' for best results. As a final task, attendees were asked to choose the one behaviour that ranked closest to red and identify one thing they could do to improve this skill.

Panel discussion:
MAPS 2030 White Paper breakdown

Presented by:

Lauren Pasfield – Senior Medical Manager, AbbVie ANZ; APPA Vice President
Simon Fisher – Director of Medical Affairs, Johnson & Johnson
Dan Thurley – APAC Informatics Network Head, Roche
Cae Tolman – Country Medical Director, Amgen

A panel featuring Simon Fisher, Dan Thurley and Cae Tolman, with Lauren Pasfield moderating, was convened to discuss the recently released MAPS 2030 White Paper. This consensus paper, written by a working group of industry experts, explores the evolving role and activities of medical affairs, including its value and role in society. It has at its core a vision for medical affairs by 2030 as 'a strategic leader at the centre of clinical development and commercialisation efforts, identifying and addressing unmet patient, payer, policymaker and provider needs that advance clinical practice and improve patient outcomes'.

The panel first discussed their key highlights from the White Paper. Cae Tolman noted that decision making has shifted from healthcare professionals (HCPs) to broader stakeholder groups. Tolman went on to say, 'We live in a world of increasingly complex therapies... this results in a need to understand the breadth of scientific data and the needs of each individual stakeholder while translating it to them in a language that they understand.'

Simon Fisher discussed the place of medical affairs in the broader healthcare ecosystem and its role in evidence generation. He noted how the environment has changed dramatically since 2014, with the patient now being more informed and with the advent of telehealth. Fisher also noted how the role of the external-facing individual is shifting from commercial teams to scientific teams as HCPs now prefer to engage with medical experts rather than sales teams. As a final comment, he emphasised the increasingly important role of real-world data and registries.

> 'Medical affairs will be a strategic leader at the centre of clinical development and commercialisation efforts, identifying and addressing unmet patient, payer, policymaker and provider needs that advance clinical practice and improve patient outcomes.'

In contrast to Fisher and Tolman, Dan Thurley pointed out what he believed were missed opportunities saying, 'The risk with a consensus paper is you don't get the extremes, you get the consensus in the middle…I thought there was an opportunity for some bigger, bolder proposals for us.' Thurley commented on 'the elephant in the room' — namely that pharmaceutical companies are for profit organisations — remarking, '…I was a little bit surprised not to see making a profit for a company anywhere in here… to ignore that in any conversation somehow leaves an elephant in the room… it can actually undermine people's trust in the conversations they're having'.

The role of big data and AI in medical affairs was also examined, with Thurley underscoring the risks involved. 'The opportunity for AI is great, but there are risks that need to be considered', he remarked. Thurley stressed the need for Australia to collaborate internationally to obtain large data sets quickly, noting, 'with a small population, Australia cannot obtain data quick enough without it becoming obsolete…'

Simon Fisher, Lauren Pasfield, Dan Thurley, Cae Tolman

A final topic of conversation was what success will look like in 2030 for a medical affairs team. Tolman saw success for medical affairs teams of the future as engaging with stakeholders through multiple channels, bringing the right insights through direct engagement and through big data.

Plenary Session:

Embracing innovation in digital health: Are we ready?

Presented by:

Alex Condoleon – Head of Digital Healthcare; General Medicines, Sanofi, USA,
Sarah Clark – Global Head of Medical Affairs and Operations; Biogen Digital Health, Switzerland
Dr Raghav Murali-Ganesh – Co-founder, CEO of CancerAid
Dr Mark Phillips – Head of Clinical Research and Medical Affairs, Annalise.AI Australia
Session chaired by Bevan Sweerts – Senior Medical Manager, Sanofi; APPA Secretary

Alex Condoleon opened by remarking, 'It's very clear that technology is at a point of maturity where it can play a role in impacting healthcare'. Condoleon's presentation encompassed two topics: what are the business models for digital health and how are business model evolving to embrace digital. He first discussed how digital technologies can impact the value chain for payers. Digital technologies can lift research and development productivity by rapidly identifying molecules — through data and analytics — likely to succeed, saving billions of dollars. Furthermore, effective digital technologies can aid in the efficient execution of clinical studies by improving patient identification and making it easier for patients to engage with clinical study operators. Condoleon discussed how digital therapeutics are helping HCPs treat diseases, commenting, 'Forecasts project that we will see more prescriptions for digital therapeutics by mid-2030 than what we are currently seeing for conventional therapeutics.'

Sarah Clark spoke next about personalised and digital medicine in neuroscience. Currently, Biogen are looking at ways to incorporate digital health into current clinical practice. Clark defined digital health as the use of advanced technologies to improve healthcare and the practice of medicine. Digital medicine, a subset of digital health, examines biomarkers or ways to monitor or intervene in health. Digital therapeutics, the final category within digital health, is associated with treating and managing a disease. Clark proceeded to showcase digital technologies currently in development at Biogen, including Konnectom, a platform to support real-world evidence generation; AI SQUARED, an FDA-listed algorithm used to identify, quantify and classify amyloid-related imaging abnormalities (ARIA); and Physio.me, an exercise platform that provides at-home tailored exercises for those with neuromuscular disease.

Dr Raghav Mirali-Ganesh was next to present and discussed behaviour change and self-management in oncology. Currently, the incidence and survivorship of cancer is increasing, with these trends placing a significant cost and burden on health systems globally. Dr Mirali-Ganesh and his team developed the CancerAid Coach Program — designed to deliver a high scale, seamless patient and coach experience facilitated by digital technology. Dr Mirali-Ganesh highlighted that, on average, 91% of patients complete the CancerAid Coach Program with a 98% satisfaction score; there are over ten peer-reviewed publications; and, most importantly, for every dollar invested claim costs are reduced by $6.50.

The final speaker, Dr Mark Phillips, presented on annalise.ai — an imaging algorithm that can detect and identify anomalies on X-ray and CT scans. Dr Phillips remarked on the power of AI in medical imaging and the unmet need; approximately 70% of patient chest X-rays are normal. Dr Phillips added, 'The fact that an average chest X-ray gets read in about 60 seconds becomes a little more concerning…' Dr Phillips and his team were able to train their AI, annalise.ai, using vast amounts of X-ray and CT scan data, to identify areas of interest on a scan. A hospital in the United Kingdom National Health Service deploying this AI for 3 months was able to detect 12% more chest and lung nodules compared to prior methods. Dr Phillips also discussed the use of AI to predict disease outcomes, specifically in patients with chronic obstructive pulmonary disease (COPD). Using patient data, such as heart rate, respiratory rate and oxygen saturation, the AI can predict when the patient is going to experience an exacerbation many days before symptoms manifest, allowing the patient to medicate at an earlier time point.

Plenary Session:

Collaboration is the most effective catalyst for change – patients are losing their patience

Presented by:

Krystal Barter – Founder of Humanise Health Australia
Kerry Chikarovski – Former leader of the opposition NSW legislative assembly
Associate Professor Wendy Ingman – Adelaide Medical School
Shelly Horton – Journalist and Co-founder of Don't Sweat It

This plenary session was a panel discussion of the challenges and realities of patient advocacy in Australia, how to empower patients to approach government and the burden of advocacy.

Krystal Barter opened the session by sharing her experience as a patient who is a carrier of the cancer-causing genetic mutation, *BRCA1*, to highlight the role of health advocacy in healthcare. Barter said, 'When I was having my breasts removed, there wasn't a breast care nurse for me. There was nothing that I could access, yet I was having a test that should be mainstream'. Barter questioned at the time why no one was discussing genetic testing or talking to government to enable better access. At this time, the United States (US) was more progressive than Australia in relation to patient advocacy, with Barter stating, 'Government didn't want to talk [to us], except for a few ministers'. Barter believes that the role of advocates is to shed light on inequities, injustices, and a lack of support in order to precipitate change.

> "We are the taxpayers. We should be able to contribute to conversations that lead to change."

Kerry Chikarovski detailed the problems that patient advocates face when talking to government, noting, 'The problem is that everybody goes to government to solve every problem… The reality is government neither has the ability, funding, nor the priorities.' She added, though, that governments have realised that prevention is a more cost-effective long-term measure; however, the problem now is how to cut through the noise so as to become a priority.

The discussion next addressed the role of academics in the advocacy space. A/Prof. Wendy Ingman noted that there has been a shift in academia's relationship with consumers of late. A/Prof. Ingman, an advocate for breast density notification in Australia, gave as an example the fight between patients and clinicians in the US, where clinicians argue that patients should not be notified of their breast density because of issues around how to use that information. Breast density reflects the amount of fibrous and glandular tissue in a woman's breasts which appears 'white and bright' on a mammogram. It is a risk factor for developing breast cancer and can also mask cancers on a mammogram. A/Prof Ingman said, 'Patients were arguing that it's their right to know, and it is their right to know; patients should be involved in their own healthcare decisions'.

The burden associated with patient advocacy was the next topic discussed. Barter described the difficulties she experienced in advocating for clinicians to inform women about their breast density in Western Australia (WA). Clinicians argued that they did not want to tell women about their breast density because they would become anxious, and that there was a lack of morbidity data.

A/Prof Ingman added that, 'There was no cost benefit analysis because the evidence wasn't there… it would take years to get morbidity data'.

Chikarovski suggested there are three areas patient advocates need to do consider when presenting their arguments to government: 1. Find alliances and third-party endorsements. 2. Be clear about what you are asking for. 3. Consider the cost implications.

Shelly Horton, Krystal Barter, Wendy Ingman and Kerry Chikarovski.

> "Governments need to know that the money they're spending is being well spent."

The panel wrapped up the plenary session by outlining practical tips for patient advocates. Barter noted that, although industry attitudes to carers and advocates has changed for the better, it can still be difficult for patient advocates to work with industry. Barter said, 'I think it's about conversations; it's about looking at the problems together and looking for solutions'. A/Prof. Ingman emphasised the role of academics, saying, 'Academics are a critical part because we bridge the gap between patients and their experiences and translate that into healthcare. You can't change anything without evidence'. Chikarovski mentioned that the most important detail to remember when talking to politicians about your needs is, what is the ask; what is it you want the minister or the government to do?

As a final remark, Chikarovski advised, 'Make sure you do your research, and make sure that when you are asking them to do something that they can do it within their means'.

Workshop:
Professional development standards in medical affairs

Presented by:

Orin Chisholm – Program Director, Pharma/Medical Device Development, University of Sydney
Victoria Elegant – VP and Region Head, JAPAC, Amgen
Matthew Britland – Medical Direct, Amgen; APPA President
Andrew Weekes – Senior Director of Medical Affairs, Gilead

This informative workshop examined strategies for developing professional standards in medical affairs. Specifically, this workshop focused on whether medical affairs would benefit from a competency framework, accredited training offerings and having a professional accreditation body, as well as what these offerings could look like and the steps required to make them a reality. A competency framework in medical affairs was first discussed, with results from previous surveys indicating that most respondents thought that the medical affairs profession would benefit from a competency framework, accredited training offerings and that MAPA would be the most appropriate peak body. Attendees were divided into groups and asked to discuss and provide feedback on these survey results. Most groups, except one, were supportive of a competency framework, with the dissenting group expressing concern that it may be too restrictive for those aspiring to join the industry. Attendees also agreed that the framework could be a useful staff development tool, particularly for identifying gaps in knowledge and competency so that staff can be trained appropriately.
The workshop also examined existing frameworks in other countries and how they can be adapted to the Australian environment. Participants were asked to discuss exactly what skills and competencies should be included in the framework. Skills highlighted included business acumen, engagement skills, agility, digital communication and collaboration.

Workshop:

Evolving the medical communication strategy: A purist vs. pragmatic approach, or a bit of both

Presented by:

Beejal Vyas-Price – Global Scientific Communications Manager, Cochlear
Amy Kavka – Omnichannel Medical Communications Senior Manager, Amgen

This highly engaging interactive workshop, moderated by Beejal Vyas-Price and Amy Kavka explored how to build an effective medical communications strategy that ensures a consistent scientific and strategic narrative. The first session discussed the definition of an Integrated Medical Communications Strategy (IMCS). An IMCS links insights to tactics via a medical strategy to help create a cohesive consistent scientific narrative across multiple channels and formats. As part of the first session, attendees were asked to describe the insights each role in medical affairs brings to medical strategy as well as actionable insights. The next session discussed what a scientific narrative is and why it is important in an IMCS. To summarise, a scientific narrative should draw in the reader, communicate the facts in a clear and compelling way, guide the reader through the events and highlight the meaning and significance of the events. Participants were instructed to create their own scientific narrative based on a fictional disease, APP-CoV-2022, and treatment. In the final session, attendees were asked to consider how they would move from a scientific narrative to a tactical plan using brand strategy, medical strategy and medical communications objectives.

Closing Keynote:

MA on MA

Presented by:

Elizabeth de Somer – CEO Medicines Australia

'Health is now permanently linked to productivity in the economy…' was the first message from Elizabeth de Somer. De Somer continued, 'Consumers have also changed. They are no longer passive recipients of information; they expect and demand to be central to their healthcare decisions…'
The main topic of De Somer's presentation was the Health Technology Assessment (HTA). The HTA review is part of Medicines Australia's strategic agreement with the government, and it is an opportunity to educate and raise awareness about what access to medicines should look like in Australia. De Somer began by remarking that we should be seeing immediate access to medicines in Australia once they have been fully researched, presented to the TGA, are proven to be safe and effective and produce results. To achieve this, De Somer stated, 'In order to be immediately available… there has to be a policy change, and there has to be a policy imperative…'

> "We want Australian patients to have first, fast access to the best treatments…"

De Somer spoke about the productivity benefits of keeping Australians healthy. 'There is clearly an imperative to demonstrate the productivity benefit of every innovation that we bring to patients,' De Somer said. There is a productivity benefit for patients staying healthy so they can contribute to society, pay tax, and not be dependent on welfare. De Somer argued that we need a policy aspiration for health similar to that for education, citing federal politician Chris Bowen's words, 'If we educate our children to year 12, we increase our GDP by 8%...' as a desired example.
De Somer highlighted how the public do not understand the value and investment of manufacturing medicines, and that we are seeing older and cheaper medicines being undervalued and withdrawn. Furthermore, with new innovations on the horizon, the Australian government expects to pay a comparable price to cheaper medicines.

'We don't value the incremental benefit of taking it once-a-week instead of once-a-day,' De Somer said by way of example. As a solution, De Somer argued that if we can capture, value and quantify real-world incremental increases in productivity and quality-of-life benefits then we will be able to properly value medicines. As a start, De Somer suggested we need to raise awareness about the importance of medicines and the medical system

As a final call to action, De Somer declared that the medical industry needs to stop talking to itself and instead focus on what clinicians, patient groups and hospitals wants and expect, stating, 'We need this to be a collective voice, not just from the industry, but from the community... we should all be asking for the same thing and we need a common goal... we should all be driving to the same outcome.'

> "We need to make sure that our message is clear and united. The value of innovative medicine needs to be understood."

Elizabeth de Somer, CEO Medicines Australia

This newsletter was produced by McCann Health Australia in partnership with MAPA.

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