



**MCIA**

Medicinal Cannabis Industry Australia

# Annual Report 2021-22

A not-for-profit member driven organisation

# Contributing value to the medicinal cannabis industry

MCIA works within six pillars of activity to enhance value to the industry and members, and deliver on the vision of  
*“Building an industry that enhances wellbeing through facilitating access to quality Australian medicinal cannabis products for Australian and global patients, and where the industry and its products are built on sound science and underpinned by industry processes and standards that ensure patients, the medical community and governments have confidence in the sector and its products, services and information.”*



Elevating industry standards and initiatives that enables patient access to trusted products, underpins innovation, and drives a culture of integrity, transparency and fairness across the medicinal cannabis industry.

Targeted advocacy with balanced, contextual and inclusive representation, and promotion of industry issues.

Advocate for key policies and outcomes to support the sector including in areas such as patient access, regulatory efficiency, harmonisation and compliance, product integrity.

Sharing of experiences information and ideas to contribute to a collective knowledge that supports confidence in the medicinal cannabis industry and its products.

Build confidence with patients, doctors, the healthcare sector, community and Government through the MCIA Code of Conduct and other technical guidance documents. Trust and integrity are the cornerstones of a sustainable medicinal cannabis industry.

Identify and support local and global growth opportunities for the industry.

Lift the industry voice to influence policy and regulatory developments, contribute to public debates, promote policy and data through proactive advocacy, and foster industry leaders.

Connect, inspire, and support the medicinal cannabis ecosystem to help build a responsive and agile industry.

Directly interface with government and other key stakeholders.

Increase awareness and knowledge and improve connectivity through networking and information opportunities for members and events such as ACannabis.

Work collaboratively with regulators to promote and shape a framework supportive of delivering Australian quality products to Australian patients in a timely and affordable manner.

Work with our members to develop industry standards, codes of practice, technical guidelines, etc in order to improve transparency, fairness and patient/healthcare practitioner confidence.

# MCIA Board



**Peter Crock**  
Chair MCIA & CEO,  
Cann Group



**Elisabetta Faenza**  
CEO, LeafCann Group



**Russell Harding**  
Executive Chairman  
and CEO, MedReleaf  
Australia



**Patty Holmes**  
Director and  
Co-founder, Holmes  
and Wilson



**Carol Ireland**  
CEO and Managing  
Director, Epilepsy  
Action Australia, and  
MCIA/MCC  
collaboration, patient  
advocate



**Jo Patterson**  
CEO, BOD Australia

# MCIA Committees

## Board Committees

- Membership Committee
- Communications Committee

## Working Groups

- Policy Working Group
- Research Working Group
- Standards Working Group

# MCIA Working Groups

## Policy Working Group



Chair:  
**Dr Jaroslav Boublik**  
CEO Research & Advisory and  
Chief Scientist, LeafCann Group

The Policy Working Group is responsible for assisting MCIA and the Board develop formal position statements on key policy issues; monitor and report on Federal/State and global legislation/policy trends and recommend MCIA response as appropriate; and develop industry positions/submissions in relation to Government, regulatory and other relevant inquiries and consultation.

The Policy Working Group was very active during 21/22 year with development of policy positions/papers or submissions to:

- Medicinal Cannabis Permit Reform (Office of Drug Control (ODC))
- Risk-based variations (ODC)
- ODC Transformation project
- Medicinal cannabis reforms (updated TGO 93) and associated guidance
- Delta-8 Tetrahydrocannabinol (Delta-8 THC) position paper (TGA)
- Road Transport Amendment (Medicinal Cannabis) Bill 2021.
- Royal Commission into Veteran Suicides
- MCIA submission in response to TGA consultation on S7 for research purposes

## Standards Working Group



Chair:  
**Elisabetta Faenza**  
CEO, LeafCann Group

The Standards Working Group is responsible for assisting MCIA and the Board to develop and maintain a self-regulatory, principles-based Code of Conduct for the industry (and any associated Guidelines or Protocols); and inform the development, effective and efficient operation of relevant standards to be adopted across the industry.

The major activity for Standards Working Group in 2021/22 was a review of the MCIA Code in light of the updated TGO93, which resulted in Version 2 of the Code being released.

Ongoing activity is focused on advertising compliance and GMP compliance for imports.

The Standards Working Group is also investigating the opportunity for best practice guidance documents and development of tools to assist members in identifying and complying with regulations and standards.

## Research Working Group



Chair:  
**Melinda Thompson**  
Head of Regulatory Affairs &  
Quality Systems, Source Certain  
International

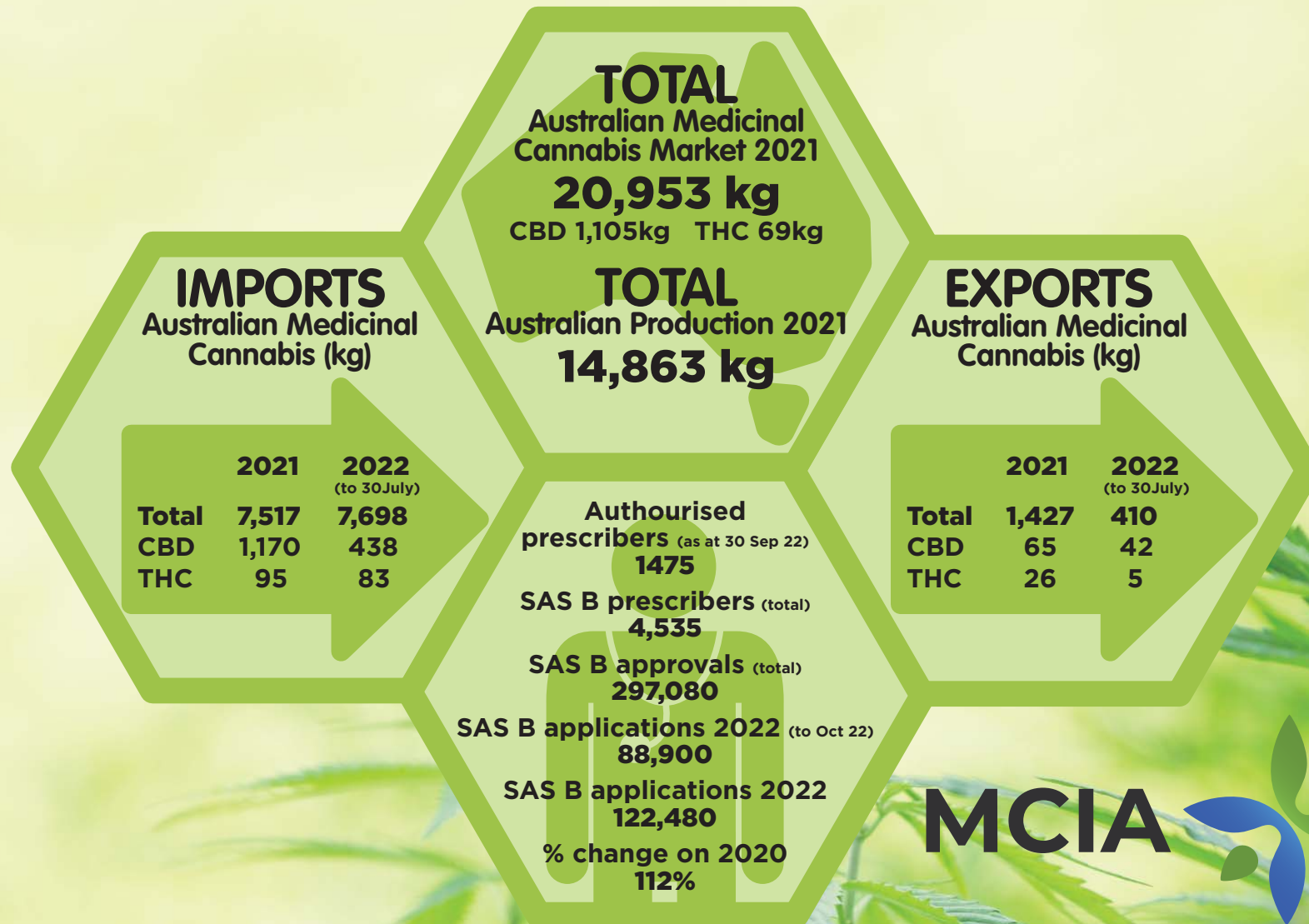
The Research Working Group is responsible for assisting MCIA and the Board to:

- Facilitate the sharing of knowledge and expertise regarding clinical trials, observation studies, product pathways and related activities
- Identify commercial, regulatory, ethical and legal impediments to the execution of research pertaining to medicinal cannabis in Australia
- Identify opportunities for research collaborations and partnerships that would benefit the industry as a sector and/or the broader community
- Engage with political, regulatory and other stakeholders to facilitate information exchange and educational activities pertaining to medicinal cannabis.

Key focus for the group in 2021/22 was around

- Scheduling of cannabis for RESEARCH into therapeutic use
- Survey of research organisations to identify constraints and challenges for medicinal cannabis research activities
- Communication and engagement strategy in regard to Human Research Ethics Committees (HREC) and hosting of workshop to discuss approaches to successfully engaging with HRECs in the area of clinical trials involving unregistered medicinal cannabis therapeutic goods
- Discussions with potential funding bodies for insight into possible funding of an industry wide research strategy

# Australian Medicinal Cannabis<sup>1</sup> Market at a glance



<sup>1</sup> "Cannabis" is dried cannabis flower. "THC" and "CBD" are reported as 100% pure equivalents  
 "Net" is local production, plus imports, minus exports. Measurements are in kilograms

Source: ODC FOI request TGA

<https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-access-pathways-and-patient-access-data>

# Chair Report

It is with pleasure that I present this report to the 4th Annual General Meeting of the Medicinal Cannabis Industry Australia (MCIA).

After decades of relative stability in geopolitics, global health, and the global economy, the past 12 months have reminded us that as businesses and as a society as a whole, we need to remain nimble, adaptable, flexible, and forward looking. Fortunately, Australia has weathered this period relatively well, rebuilding as we emerge from COVID 19 restrictions.

Our industry continues to mature and the medicinal cannabis ecosystem is developing, although challenges remain for patients, prescribers and companies. I have said previously that the success of our industry depends upon a mature approach to policy-making, a commitment to quality, adherence to high ethical standards; and improved access pathways for healthcare consumers.

Unfortunately recent months have highlighted that not all of our industry is yet aligned around these principles, making the MCIA approach and tools such as the MCIA Code of Conduct ever more important. MCIA will continue to work across our ecosystem to promote good practices, develop tools to support good behaviour, and support education activities for the whole sector.

The reforms to TGO 93 announced in March this year will be a significant boost for the local Australian medicinal cannabis sector, and for patients. MCIA has been advocating for some time for a level playing field to address potential issues of patient safety and to ensure Australian based companies have a fair opportunity to participate in and shape the industry. While there is still work to do, this

was a very significant shift for the sector. MCIA is continuing to work with the Government in relation risk based policy, and compliance imported products with GMP and biosecurity requirements.

The MCIA Board undertook a review of the MCIA strategy during the year and endorsed the organisation's vision is for an innovative, responsible and legally compliant industry delivering both economic and social value while focusing on individual well-being. During 2021/22 MCIA released "A Roadmap for Australia's medicinal cannabis industry", which provided insight to the opportunities, challenges and pathways to success for the industry. MCIA has, and will, continue to advocate for and implement strategies to deliver against its vision and the roadmap.

MCIA has delivered on a number of planned initiatives during the year including ACannabis - the industry's conference. While not able to meet in person, ACannabis again brought the industry together from across the ecosystem to share ideas, learn from each other and explore opportunities for our exciting industry. We are very excited to be back in person for ACannabis 2023 at Melbourne's new showpiece venue - Centrepiece, and I invite you all to be part of ACannabis 2023.

Dr Richard Di Natale through his role of Chair of the Medicinal Cannabis Health Advisory Council has worked closely with the Royal Australian College of GPs (RACGP) to advance an accredited training program for prescribers as a precursor to developing streamlined access pathways for prescribers and patients. It is pleasing that RACGP is supporting this and is working with Dr Di Natale to progress this.

MCIA continues to have a very active engagement with the Government, various regulatory authorities and members of Parliament. MCIA has built sound relationships with the regulator and continues to work collaboratively to promote and shape a framework supportive of delivering Australian quality products to Australian patients in a timely and affordable manner. A major part of our activity has been around advocating for key policies and outcomes to support the sector including in areas such as patient access, regulatory efficiency, harmonisation and compliance and product integrity.

We have continued to hold regular meetings with the Office of Drug Control (ODC) and Therapeutic Goods Administration (TGA), with both these organisations regularly participating in our member forums, and have made a number of comprehensive submissions to various inquiries. These are listed elsewhere in the Annual Report, but I would like to single out the work and outcomes of the in relation the updated TGO 93 and guidance for the industry. Through our members and the working groups we have both highlighted areas for clarification and correction, and assisted TGA to develop more user friendly and targeted guidance documents.

I said last year that the value of MCIA is demonstrated through these activities and our submissions and shows the power of like-minded organisations coming together to express different views, have constructive discussion, supported by investment in evidentiary research to develop a well articulated and robust submission that will deliver improved outcomes for patients, the community and industry.

Activity by MCIA with Austrade and Global Victoria cumulated in Australia's first presence on the global stage with an Australian delegation and trade stand at the ICBC in Berlin in July. The feedback from all those who participated as well as our Federal and State Government colleagues has been very positive and I am sure will just be the first of many such activities to come.

Our industry and its products have the opportunity to have a profound impact on the way we treat some conditions, the potential to improve the wellbeing of a wide range of patients, and to contribute positively to Australia's health system. Australia is well placed to lead the world with quality medicinal cannabis, deliver next generation patient wellbeing, and develop a new export industry. However, as an industry, we need to step up and ensure that we are behaving appropriately and to the highest standards. It is important as an industry that we provide the stewardship and evidential support to see it become part of healthcare options available to patients. MCIA will continue to play a leading and very strong role in supporting this.

It has certainly been pleasing to return to face-to-face meetings and networking activities this year, and provide the ability for members to exchange views within meetings and network with each other. The MCIA Board strongly believes that this collaborative nature of the MCIA membership underpins the value of MCIA to members and the industry. MCIA continues to be the voice of the industry, advocating to Government and other sectors for the betterment of the Australian medicinal cannabis industry. We greatly appreciate your support and input which provides important guidance and technical capacity for MCIA.

However, it is important that we continue to grow our membership and I encourage you all to invite colleagues and others in the sector to join MCIA.

I would particularly like to thank the members of our working groups which continue to do much of the heavy lifting, and all our new members who have joined us over the last year. Your collective support and involvement has enabled MCIA to progress on as many fronts as possible. In particular, I would like to thank my fellow board members - Russell Harding, Elisabetta Faenza, Carol Ireland, Patty Holmes and Jo Patterson, and also acknowledge the contribution of Cronos CEO Rodney Cocks, a director of MCIA since July 2018, who left the board in February 2022.

Lastly, I invite you all to attend ACannabis 2023, which, will be in-person in Melbourne on 14 & 15 March 2023. ACannabis has put the Australian medicinal cannabis industry centre stage and helped improve communication and understanding of needs and requirements across patients, industry and Government.



I have enjoyed the privilege of leading this very important and vibrant industry association since its inception, and look forward to continuing working with everyone that is part of this exciting new industry to ensure that it delivers positive outcomes and impact for all. MCIA wants to be your trusted partner in shaping the Australian industry, facilitating access for patients and enhancing Australia's place in the global medicinal cannabis industry. I am confident with the MCIA membership and team that we can achieve this.

**Peter Crock**  
Chair  
Medicinal Cannabis Industry  
Australia (MCIA)



# Objectives

Medicinal Cannabis Industry Australia (MCIA) is the peak industry organisation for Australia's licensed medicinal cannabis industry. It represents the mutual interests of members and other stakeholders to build a professional industry based on legitimacy, credibility and recognition for the Australian sector in domestic and international arenas. It acts as the voice for the licensed medicinal cannabis sector.

Specific objectives are to:

- facilitate and promote the growth, development and reputation of the medicinal cannabis industry
- promote regulatory consistency across Australia and facilitate a self-regulatory environment that accelerates access for Australian products to Australian and global patients
- promote awareness and confidence in medicinal cannabis
- promote best practices in all aspects of the industry's operations

# Industry Outcomes

MCIA, through its activities, will support/develop:

- Well informed patients, healthcare sector and industry, based on sound data and research
- A better skilled industry - operating at best practice
- Access to more effective tools and processes
- A harmonious and collaborative industry which works to grow the industry within the context of community and environmental responsibility
- Enhanced innovation and leadership
- A legitimate and legally compliant industry





# Highlights of 2021/22

## Government Relations activity

## Advocacy/Stakeholder engagement

During the year, we saw a new Minister and Assistance Minister for Health and Ageing. MCIA met with Assistant Minister Ged Kearney in July very shortly after her appointment to the role, and welcomed her support for the medicinal cannabis industry.

A core activity for MCIA is working with regulators and other stakeholders to help shape the regulatory environment, in particular, over the past year MCIA has worked closely with:

- TGA on the Medicinal cannabis reforms (TGO 93). Our industry will benefit substantially from all parties having to comply with GMP standards.

- TGA through ongoing engagement with TGA on advertising guidelines and compliance, import protocols, scheduling, testing and compliance, compounding, and representation on key TGA Working Groups
- ODC on Medicinal Cannabis Permit Reform, Compliance & Monitoring Framework, and the ODC performance. MCIA has responded to a series of reviews and reforms in regard to ODC, and have worked with ODC to develop solutions for the industry including single license, permit reforms, risk based compliance framework, and the ODC transformation project.

Other activities include:

- Development of briefing papers and policy statements
- Engagement with the State and Federal Government, regulatory authorities, Advisory Councils and members of Parliament
- Engagement with patient advocacy groups, medical sector and other community stakeholders

## Submissions

- ODC - Engagement on Medicinal Cannabis Reforms- Licence and Permit Transition  
**AUGUST 2021**
- TGA - OOS Imports & Delta-8 products  
**NOVEMBER 2021**
- ODC Compliance and Enforcement Framework  
**JANUARY 2022**
- TGA - Proposed Amendments to the Poisons Standard (Medicines/Chemicals)  
**JANUARY 2022**
- TGA - Feedback on draft TGO 93 changes  
**MARCH 2022**
- NSW Legislative Council's Standing Committee on Law and Justice inquiry into the Road Transport Amendment (Medicinal Cannabis -Exemptions from Offences) Bill 2021  
**APRIL 2022**
- TGA - Compounding  
**MAY 2022**
- ODC - Risk Based Approach to Notifications and Variations  
**JUNE 2022**
- ODC - MCIA priorities re ODC transformation project  
**AUGUST 2022**



# Highlights of 2021/22

## Industry governance

Medicinal cannabis has an important role to play in improving health outcomes, and has demonstrated its potential to positively contribute to a broad range of conditions. MCIA supports easy and affordable access by patients to a quality controlled, true to label, compliant product. A core focus for MCIA is working with industry to develop a culture of doing things the right way, ethically, with integrity, and in full compliance with the law, with a view to building the trust and confidence of all communities with which MCIA members engage.

The MCIA Code was developed to help build confidence with patients, regulators and the community. The Code also contributes to and support a well-functioning medicinal cannabis industry. MCIA has said many times we are seeking to build a trusted industry, and this will be achieved if the industry can demonstrate a culture of doing things the right way, ethically, with integrity, and in full compliance with the law.

Following changes announced to TGO 93 and other regulatory reforms, MCIA reviewed the Code during the 2021/22 year, and released Version 2 of the Code in July this year.

The Code addresses issues that have potential to impact on the integrity and reputation of the medicinal cannabis industry. The importance of this has been highlighted with recent actions by TGA in relation to companies not acting in compliance with TGA advertising guidelines. The Code will assist MCIA members to be recognised as committed to developing and operating in an industry that is built on trust, accountability, and assurance. The Code aims to promote high standards of integrity across the medicinal cannabis industry so that patients and healthcare professionals can have confidence in their dealings with the Industry and its members and their products.

## Representation

- 3rd Forum of the Colombian Association of Cannabis Industries - Asocolcanna  
Australia's Medicinal Cannabis Journey,  
Peter Crock MCIA Chair  
**NOVEMBER 2021**
- Uruguayan Chamber of Medicinal Cannabis Companies (CECAM)  
Australia's Medicinal Cannabis Journey,  
Peter Crock MCIA Chair  
**DECEMBER 2021**
- German-Australian Chamber of Industry and Commerce  
Australia's Medicinal Cannabis Journey  
Rosemary Richards Executive Manager MCIA  
Exporting to Germany - commercial considerations, Peter Crock CEO Cann Group  
**MAY 2022**

## Supporting Industry growth

MCIA has increased its activity around quantifying industry metrics and continues to provide members with information and insights to navigate, often complex, industry issues. MCIA released its Roadmap document in May this year which outlined Opportunities and Future Direction for the Medicinal Cannabis Industry.

MCIA successfully facilitated a global presence for the Australian medicinal cannabis industry, in partnership with worked with Austrade and Global Victoria. This enabled the industry to have an Australian presence at the International Cannabis Business Conference (ICBC) in Berlin in July and at the ICBC Global Investment Forum



# Highlights of 2021/22

## Education

The medicinal cannabis Health Advisory Council, under the leadership of Dr Richard Di Natale has been active over the past year in working with the Royal Australian College of GPs to develop an accredited training course for prescribers.

The Council is committed to ensuring that there continues to be a strong focus on facilitating patient access to medicinal cannabis, that there is access to balanced evidence based information for patients, and education and training programs for the medical profession that will enable improved communication and access pathways for medicinal cannabis.

## Patient access

MCIA continues to actively working with Drive Change and other stakeholders to advocate for changes to driving laws, which has been identified as a major barrier to increased patient access. Additionally direct state advocacy activities include MCIA submissions to Victorian and NSW Government inquiries.



## Building the medicinal cannabis ecosystem

### Engagement and networking

Building our ecosystem is critical and alongside MCIA's mantra of "Shaping the industry for patient wellbeing", MCIA is also focused being "Your connection to Australia's medicinal cannabis sector".

ACannabis 2022 again had to be held virtually but continues to be an effective forum for bringing the industry together, and is establishing its position as the premier Australian medicinal cannabis event.

MCIA was also able to get back to hosting in person networking events including:

- December 21 - Focus on export opportunities
- March 22 - Insurance for clinical trials

## Events

- Joint event with FreshLeaf Analytics and release of the FreshLeaf Analytics H2 2021 Report on Medicinal Cannabis Patient, Product and Pricing Analysis

**OCTOBER 2021**

- MCIA Networking Event - Insights into evolving medicinal cannabis export opportunities with speakers:
  - Peter Crock, MCIA Chair
  - Rosemary Richards, Executive Manager MCIA
  - George Di Scala, Deputy Director of International Market Development from Global Victoria
  - Patty Holmes, Director of Holmes and Wilson Consulting

**DECEMBER 2021**

- ACannabis - an Industry led Australian medicinal cannabis conference bringing together the industry's ecosystem

**MARCH 2022**

- Member Forums - introduced in the COVID environment to enable ongoing member contact and networking

**SEPTEMBER 2020, NOVEMBER 2020 & MAY 21**

