IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE INCLUDES:

Mexico as a Hub for Clinical Trials: A Rising Influence in Global Research

In recent years, Mexico has emerged as a dynamic and increasingly strategic location for clinical research. Bolstered by a growing healthcare infrastructure, an expansive pool of treatment-naïve patients, and supportive regulatory reforms, the country is rapidly gaining traction among global sponsors as a preferred destination for clinical trials.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Strategic Geographic and Demographic Advantage

Mexico's geographic proximity to the United States and Canada offers multinational sponsors logistical efficiencies and scalable regional operations. Its large and diverse population also presents a significant advantage for trial recruitment. With more than 135 million people spanning diverse age groups, ethnicities and disease profiles, Mexico provides access to a broad spectrum of patients, including treatment-naïve individuals, which can accelerate enrolment timelines and strengthen the statistical power of studies.

Growing HealthCare Infrastructure and Capacity

Across major urban centres like Mexico City, Guadalajara and Monterrey, investment in hospitals and research centres has elevated clinical capabilities. Many institutions are equipped with advanced diagnostic tools and experienced clinical research teams capable of managing complex study protocols. This expanding infrastructure positions Mexico to support a wide range of therapeutic areas, from oncology and rare diseases to vaccines and chronic conditions, and enhances overall trial quality and compliance.

Regulatory Reforms Supporting Clinical Research

Over the past decade, Mexico has implemented regulatory reforms that enhance the predictability and transparency of trial approvals. The Federal Commission for the Protection against Sanitary Risk (COFEPRIS https://www.gob.mx/cofepris) has modernised its review processes to align more closely with international standards reducing approval timelines and strengthening ethical oversight. These reforms have improved confidence among sponsors and encouraged greater participation from global biopharmaceutical companies.

Cost and Operational Efficiencies

Cost considerations remain a key factor for clinical trial planning. Relative to North America and Western Europe, Mexico offers competitive operational costs without compromising quality. Lower costs for patient visits, clinical staffing and facility use can significantly reduce overall study budgets. When paired with shorter enrolment periods driven by high volunteer availability, these economic efficiencies make Mexico a compelling option for sponsors operating within tight timelines and budgets.

Collaborative Ecosystem and Skilled Workforce

Mexico's clinical research ecosystem includes a growing number of contract research organisations (CROs). The pharmaceutical and biotechnological industries prefer hiring partnering companies for clinical research because they require an unbiased, neutral third party to oversee and lead team members. The pharmaceutical industry sponsors studies, and the CRO acts as a link between the company and the clinical sites that carry them out with expert principal researchers and specific patients. In addition, academic institutions and investigation sites with specialised expertise prove to be centres for patient recruitment and enrolment. These stakeholders often provide end-to-end trial support, from feasibility assessments and site selection to monitoring and data management. Additionally, the country's cadre of trained investigators and clinical staff contributes to high-quality data collection and adherence to international standards, such as ICH-GCP (1).

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Challenges and Opportunities ahead

Despite compelling strengths, Mexico's clinical trial landscape faces ongoing challenges. Disparities in healthcare access across rural areas can limit patient outreach. Regulatory processes, while improved, may still present variability across regions. Sponsors must also navigate cultural and linguistic diversity to ensure effective communication and participant engagement.

Opportunities for growth are robust. Continued investment in digital health, decentralised trial models and patient advocacy can further elevate Mexico's position. Partnerships between public and private sectors, as well as collaborations with global research networks, will continue to strengthen the ecosystem.

A Growing Force in Global Clinical Research

As the demand for efficient, diverse and high-quality clinical data increases, Mexico stands out as an attractive hub for clinical trials. Its strategic location, expanding infrastructure, supportive regulatory environment and economic advantages make it a pivotal player in global research. For sponsors seeking innovative and efficient pathways to advance therapeutic development, Mexico offers a blend of opportunity, expertise and growth potential that is difficult to overlook.

Mexico is an excellent place to carry out clinical trials for certain therapeutic indications, such as cancer, obesity, diabetes, heart problems and infectious diseases. The country has always been at the forefront and is again gaining ground in clinical trials worldwide. For several years, the clinical research arena had turned towards Asia, now returning to Latin America.

Regulatory timelines in Latin America are often perceived as longer than most, but this is mainly due to administrative requirements rather than inherent inefficiency. The region's large population coupled with the high prevalence of various conditions, makes it a promising candidate for clinical trials. Latin America boasts state-of-the-art facilities, experienced researchers and a substantial patient pool, particularly in major cities where renowned institutions and hospitals are abundant.

References

1. ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf

Author: Dr Marlene Teresa Llopiz Avilés, BA MD MPH

Dr Marlene Llópiz Avilés is currently Global Oversight Director at the PPD clinical research business of Thermo Fisher Scientific. She holds a Bachelor of Science degree from Austin College in Sherman, Texas, a Medical Doctor degree from the Universidad Anahuac School of Medicine in Mexico City, and a Master's Degree in Public Health from Harvard University with a concentration in Clinical Effectiveness. She has received honours throughout her career and has published several articles and books on Pharmaceutical Medicine and clinical research. She has twice been President of AMEIFAC (Association of Medical Specialists and Professionals in the Pharmaceutical Industry, Mexico) and was an elected candidate for the Presidency of IFAPP.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Australian HREC Clinical Trials Review Pathways and Requirements

In Australia, the importation and supply of unapproved therapeutic goods is regulated by the Therapeutic Goods Administration (TGA) via two pathways – the Clinical Trial Approval (CTA) and the Clinical Trial Notification (CTN) schemes. The responsibility for determining the regulatory pathway sits with the Sponsor first and then the Human Research Ethics Committee (HREC) reviewing the trial protocol. The Sponsor is responsible for submitting the CTA or CTN to the TGA.

The CTA scheme is designed for novel products where there is no or very limited knowledge of its safety. Certain classes of novel products, like Class 4 Biologicals are required to use the CTA pathway.

In this pathway, the sponsor will apply to the TGA and the TGA will review the scientific merit of the trial prior to ethical review by the HREC. The outcome of the TGA's review should be included in the application to the HREC. Where an application is submitted to a HREC via the CTN pathway and the HREC does not have the appropriate scientific and technical expertise to review appropriately, they can refer the Sponsor to the CTA pathway.

Another unique pathway is available in Australia, the CTN (Clinical Trial Notification) pathway. The CTN form must be submitted online prior to the commencement of the trial. In this pathway the scientific review of the trial is delegated to the HREC. The HREC undertakes the scientific review, considers the ethical dimension, and assesses site and investigator capacity and capabilities in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (National Statement, National Statement on Ethical Conduct in Human Research. The HREC undertakes a risk-benefit assessment and determines the overall scientific and ethical merit of the study.

The trial site is responsible for conducting its own governance review and providing final approval for the study to be conducted at that site. The Sponsor must ensure all required approvals are in place before the trial commences. Ongoing oversight of the trial for its duration is the responsibility of the HREC.

To conduct a clinical trial in Australia, there must be a local Sponsor that is an Australian entity. They may be an Australian subsidiary of the overseas Sponsor, a Research Institute, or a Contract Research Organisation (CRO), or other contracted party. The local Sponsor assumes full legal and ethical responsibility for the trial and provides the insurance and indemnification.

For trials that prospectively assign participants or groups of humans to one or more health related interventions, it is a requirement of the National Statement (3.1.7) that the trial should be prospectively registered in a publicly accessible register before the recruitment of the first participant. Trials are typically registered on ANZCTR or clinicaltrials.gov. The International Clinical Trials Registry Platform (ICTRP) on the World Health Organization website has a list of accepted registries

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Bellberry HREC review

Bellberry Limited is Australia's largest provider of HREC review for clinical research, overseeing more than 40% of CTN applications nationwide. It is an independent, not-for-profit organisation, which reinvests surplus funds into the research sector.

Bellberry HRECs draw on a membership pool of approximately 200 members. Each meeting is structured to ensure that every study application is reviewed by members with appropriate expertise. The member pool includes toxicologists and early-phase pharmacologists who assess all First-in-Human and Phase 1 trial applications. The HREC will review the Chemistry, Manufacturing and Controls (CMC) data incorporated in the Investigator's Brochure (IB) and may request additional information such as stability data if it is not available at the time of initial submission, or the full CMC in some circumstances.

Bellberry submission requirements and process

For clinical trials of unapproved products, the Protocol, IB, Participant Information and Consent Form are required to be included in the application at a minimum. Any other participant facing documents such as questionnaires and advertising or other documents supporting the submission should be included in the application package. For information on Bellberry's submission requirements, Sponsors and investigators are encouraged to review the guidance provided on the Bellberry website along with the National Statement.

Three or more Bellberry HREC meetings are held weekly, on Wednesday evenings. Lead site applications, along with all supporting documents, must be submitted via Bellberry's online system, eProtocol, at least ten working days before the meeting. If the submission is complete, it will be scheduled for review at a HREC meeting held two weeks after the submission cut-off date.

Comments from the HREC are provided to the investigator within two working days of the meeting. Investigator responses are reviewed outside of scheduled meetings. The time from meeting to final decision depends on the complexity and completeness of the study and the timeliness of the investigator's responses, however, the typical turnaround time with Bellberry is approximately 21 business days.

Additional sites require a separate application to be submitted via eProtocol. Additional sites in a multi-centre application are not subject to a duplicate review of the protocol. Site specific aspects are also reviewed outside of HREC meetings.

The fees for a lead site review by a Bellberry HREC and review of additional sites are available on the website (Our Fees - Bellberry Limited). These fees cover most of the lifetime of the study: pre-submission assistance, the initial HREC review, and ongoing oversight (minor amendments and routine reports and site monitoring activities). After approval, only amendments to the protocol and Investigator's Brochure incur additional fees.

Australia's dual pathway system for clinical trial approval, administered through the TGA and underpinned by ethical oversight aligned with the NHMRC's National Statement, provides a robust and flexible framework for the conduct of clinical research. The delineation of responsibilities between Sponsors, HRECs, and trial sites ensures both scientific rigour and participant protection. Within this landscape, Bellberry plays a significant role, offering streamlined processes, broad expertise, and efficient timelines that support high-quality ethical review.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Together, these elements contribute to a well-established, internationally respected system that enables timely access to innovative therapies while maintaining strong ethical and regulatory standards.

Authors:

Sally Gordon, Quality Manager, Bellberry

Kylie Sproston FTSE GAICD, CEO, Bellberry

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Belgium Launches a New Framework for Faster Patient Access, by Combining Early Access with Temporary Reimbursement

On **1 March 2026**, Belgium officially launched the **Early Equitable & Fast Access (EEFA)** framework, a major reform aimed at accelerating patient access to innovative medicines, ahead of the normal reimbursement procedure.

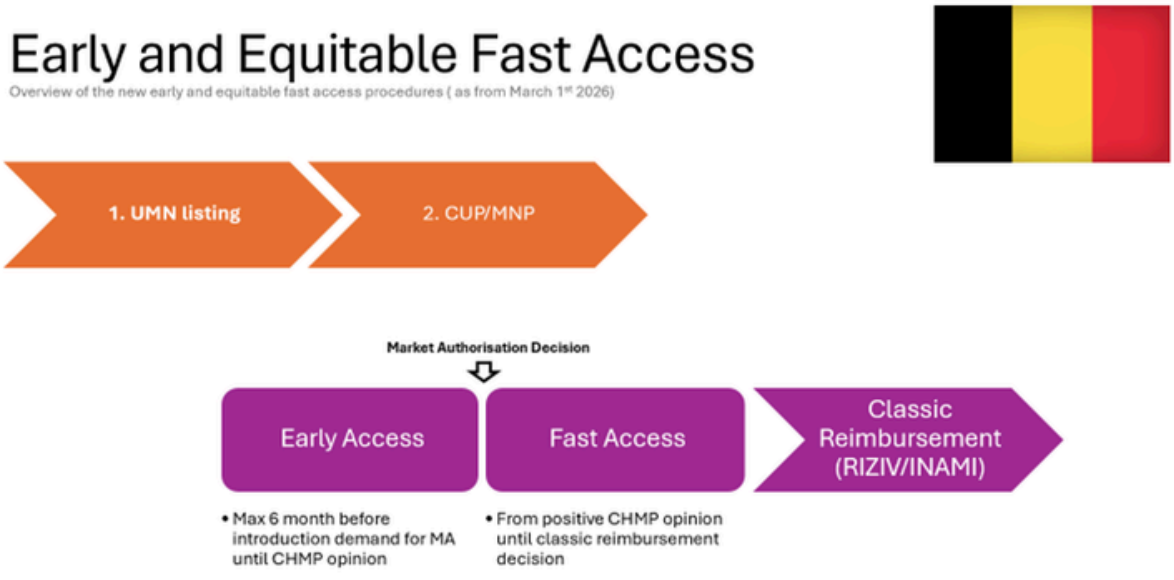
EEFA introduces a clear, structured and time-bound pathway that allows promising therapies to reach patients earlier via temporary reimbursement.

This new framework complements the existing framework of CUP/MNP (1) in Belgium and is built around two complementary pathways:

- **Early Access**, enabling availability **before approval of the European Medicines Agency (EMA)** for clearly defined patient groups with high unmet medical needs. Belgium has created a UMN (Unmet Medical Need list, ranking the medical conditions with high unmet need).
- **Fast Access**, bridging the gap a**fter EMA approval and before standard reimbursement.** Fast Access is designed for compounds which obtained an EMA Prime or Accelerated (2, 3) approval or transition via Early Access (4).

Together, Early and Fast Access create a more coherent, predictable launch and access sequence, a long-awaited improvement for patients, healthcare professionals and innovators alike.

By **combining early access with temporary reimbursement,** Belgium positions itself among the European frontrunners in enabling timely, equitable access to innovation, especially where unmet medical need is highest (5).



IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Abbreviations/References:

1) CUP/MNP: Compassionate Use Program/Medical Need Program
2) EMA Prime: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines
3) EMA Accelerated Assessment: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/accelerated-assessment
4) EMA Early Access: https://www.ema.europa.eu/en/human-regulatory-overview/support-early-access
5) RIZIV/INAME Early and Equitable Fast Access: Snellere toegang tot innovatieve geneesmiddelen dankzij de procedure Early and Equitable Fast Access (EEFA) | RIZIV

Author: Dr. Erik Present, President of Healixia and Head of Medical Affairs at Kintiga

IFAPP Fellowship Engagement

Dear IFAPP Fellows,

I hope this message finds you well and thriving in your professional lives.
As a recipient of the Fellowship Award for 2024 and 2025, you play an important role in our community.

Your achievements, perspectives and expertise enrich our organisation's mission, and we would be delighted to explore ways for you to become more actively involved in our activities.

We are currently expanding our initiatives and would warmly welcome your participation in areas such as:

- Contributing articles or commentaries to our journal IFAPP TODAY,
- Speaking or moderating at IFAPP webinars,
- Participating in IFAPP's ICPM (1) conferences, or panel discussions,
- Joining our working groups. Please refer to the Working Groups page on our website,

Sharing ideas for new projects or collaborative efforts.

We would also love to learn more about you. If you are willing, please share a short reflection on:

- Why you applied for the Fellowship,
- What you are currently working on,
- Whether and how the Fellowship has influenced your career path,
- Any interests or areas in which you would like to contribute further.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Your insights will help us to strengthen our community and shape future initiatives. With your permission, they may also be featured in our communications to inspire future Fellows and highlight the diversity of our network.

We invite you to visit our website at https://ifapp.org/ and follow us on LinkedIn. IFAPP – International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.
https://www.linkedin.com/company/ifapp/.

If you would like to engage more closely with us, please reply by email to me or to the IFAPP Board Secretary Anna Jurczynska (anna.jurczynska@ifapp.org) at your convenience. We would be delighted to hear from you.

With warm regards,
Dr Varvara (Barbara) Baroutsou
Consultant in Internal Medicine
Pharmaceutical Medicine Consultant
Research & Experimental Development in Medical Sciences Expert
CIOMS Executive Committee Member
IFAPP Im.p.President
Email: varvara.baroutsou@ifapp.org

1) ICPM: International Conference on Pharmaceutical Medicine

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The R&D Tax Incentive (RDTI) landscape in Australia

What foreign companies need to know

An iconic snapshot of Sydney, featuring the world-renowned Sydney Opera House and Sydney Harbour Bridge

Background

The R&D Tax Incentive in Australia is a national government tax credit programme focused primarily on encouraging business investment in research and development (R&D) activities. The RDTI can provide substantial refunds, improve cash flow and enable businesses to reinvest in future innovation. The RDTI is not a grant. It is contained within Australia's tax legislation system and is self-assessed and claimed annually. Based on government statistics, the RDTI is accessed annually by approximately 12,000 companies, with annual benefits of around AUD $2 billion.

Benefits available under the RDTI vary. A refundable tax offset (paid as cash) of up to 48.5% of annual R&D spend may be achievable, depending on factors such as the company's grouped revenue and tax position. Australia has long been a popular destination for global life science companies to conduct clinical trials due to benefits such as:

- Fast regulatory approval
- Cost-effectiveness
- High-quality data
- Expertise and infrastructure
- Diverse population

With the potential to also access the RDTI, Australia's clinical trial industry has seen a rapid increase in demand from overseas customers and has become one of the "go-to" places for foreign life science companies to conduct studies.

The remainder of this article highlights key RDTI considerations for foreign companies considering Australia as a destination for their R&D activities.

Eligibility

Entities

To claim the RDTI, a foreign company must be an 'R&D entity', which includes:

- Australian-incorporated subsidiary companies, or
- Foreign-incorporated companies, if they:
  - Are Australian residents, for tax purposes, or
  - Carry on business through a permanent establishment (PE) in Australia and are resident in a country with which Australia has a double tax agreement (DTA).

Most foreign groups establish a local subsidiary company in Australia to claim the RDTI.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Activities

Eligible R&D activities are defined as either 'Core' or 'Supporting' activities.

- Core activities are generally defined as experimental activities that have an unknown outcome and are conducted to test a specific hypothesis. The activities also need to be conducted for the purpose of generating new knowledge in the form of new improved materials, products, devices, processes or services.
- Supporting activities are more routine in nature but need to be directly related to the Core activities.

In 2022 the Australian government issued a 'Clinical Trials Determination Guide' that generally deems clinical trials conducted in Australia for unapproved drugs and devices and registered with the TGA (FDA/EMA equivalent) as an eligible Core activity.
Eligible R&D activities need to be conducted in Australia. The Australian Taxation Office (ATO) issued an alert in 2023 that raises questions on the ability of a foreign owned Australian company to claim Overseas R&D activities.

ExpenditureA minimum of AUD 20,000 in eligible annual R&D expenditure is required, unless using a registered Research Service Provider (RSP). All expenditure that has a link to the conduct of the Australian- based Core and Supporting activities is generally eligible.

For clinical trial activity, these expenditures may include:

- Contract research organisation (CRO) costs
- Pass throughs (e.g.):
  - Investigator and site fees
  - Biolabs
  - Biostats
- Drug substance manufacture
- Direct employees or consultants

Note: You will need to exclude expenditure for any activities that were physically performed outside of Australia.General and Administration (G&A) costs such as legal and accounting fees to set up and maintain the Australian subsidiary are also excluded.

Setting up in Australia

The Australian (AU) company will need to be incorporated prior to signing any contracts with service providers. You will also need to identify an AU resident director who will act on the board of the AU company upon incorporation. The process to set up and be fully operational takes approximately 1 to 2 months and involves the following:

- Identification of an AU resident director
- Foreign directors to apply for Australian Director Identification Numbers (DIN)
- AU company to be incorporated and registered with the Australian Securities and Investments Commission (ASIC)
- AU company to apply for relevant tax registrations with the Australian Taxation Office (ATO)
- AU company to opens a bank account with AU bank

Levels of benefit

The benefit level depends on the company's 'aggregated turnover', which includes the revenue of the foreign parent and all connected global entities.
The RDTI Tax Offsets are as follows:

- Refundable Tax Offset (43.5% or 48.5%): Available for entities with an aggregated turnover under AUD$20 million. If the company is in a tax loss position, this offset can be received as a cash refund, or
- Non-Refundable Tax Offset: For entities with aggregated turnover of AUD$20 million or more. The benefit is the company's tax (25% or 30%) rate plus a premium based on R&D intensity (8.5% or 16.5%).

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Claim process and timing

Companies must register their R&D activities with the government body 'AusIndustry' within 10 months of their tax year-end. Australian companies have a standard annual tax year-end of 30th June but can elect to change the tax year to align with that of the foreign parent company (i.e., 31st December, etc.).

After receiving the annual registration number from AusIndustry the Australian company can submit its annual income tax return with the ATO to claim the relevant R&D tax offset. For refundable R&D tax offsets, the ATO typically pays the refund amount within 1–2 months. Most companies will receive their refundable tax offsets within 2–3 months after each tax year end if they are organised and submit promptly.

Intellectual Property (IP) considerations and transfer pricing

The previous 'own behalf' rules implied that the AU company needs to own results, control and bear the financial risk associated with the work conducted in Australia. However, a change under the new program in 2011 now allows the work to be conducted for the benefit of the foreign parent company. While the ATO has not been prescriptive on what sorts of arrangements need to exist in relation to IP, there are essentially two models that the ATO and most tax advisors in Australia understand:

1) Australian owned

- Own behalf test needs to be satisfied (i.e., based on the overall substance of the relationship between foreign parent and AU company).
- The AU project is conducted for the benefit of the AU company with the ability for it to generate or share in the commercial exploitation of the results.
- Intercompany legal agreements between the foreign parent and AU company generally provide access to existing and new IP.
- AU company will own commercial rights to any new IP generated.
- Transfer pricing study may be required regarding economic benefits accruing to AU company and arrangements around intercompany IP licenses, assignments, etc.
- AU company can potentially get up to 48.5% RDTI refundable offset on R&D spend but may need to pay tax at 25% or 30% company tax rate on future revenues from commercialising the IP generated.

2) Foreign owned

- No project results or IP owned by AU company (i.e., own behalf test does not need to be satisfied).
- Foreign parent needs to reside in a country that has a DTA with Australia.
- The AU project is conducted for the benefit of the foreign parent, which will retain full rights to commercialise the results.
- Intercompany legal agreements between the foreign parent and AU company are required under an R&D services arrangement whereby AU company needs to be remunerated on 'arm's length' terms.
- Transfer pricing study may be required to determine appropriate revenue to recognise by AU company for R&D services provided.
- AU company can potentially get up to 48.5% RDTI refundable offset on R&D spend but will need to pay tax at company tax on R&D services revenue. Net cash benefit is approximately 18.5% on annual R&D spend.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Documentation and audit risk

There is a requirement to keep contemporaneous records that evidence novelty and the conduct of the R&D activities. Under ATO legislation and Corporations Act requirements, the Australian company is required to maintain and keep adequate books and records. The ATO and AusIndustry audit a small sample of RDTI claims lodged annually and can investigate claims before or after they are paid. Both government agencies can unwind and deny claims paid in a prior year and impose repayment obligations, with penalties and interest.

About Prime

Prime Financial is an Australian Securities Exchange (ASX) listed financial services organisation - www.primefinancial.com.au.

Prime's accounting and business advisory team has been providing specialist R&D tax services for more than 20 years.

Our team can deliver the following services:

- Undertaking an eligibility assessment of your current or planned R&D activities
- Advice on structuring inter-company arrangements to maximise benefits under the R&D Tax Incentive program, while managing legal and tax issues when commercialising technology
- Setting up the required Australian companies and providing necessary compliance, ongoing accounting, and taxation support
- Advice on documentation required to support a successful claim and any audit activity that may arise. Preparation and lodgement of the annual claim.

Author:
Brendan Brown brendanb@primefinancial.com.au – Partner & Director, Prime Accounting & Business Advisory with over 20 years experience assisting foreign life science companies navigate the complexities of the Australian RTDI programme
Affiliations: Registered Tax Agent, Chartered Accountant

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

IFAPP Collaborations: New Partnerships

Through partnerships, we want as IFAPP to collaborate with organisations that have the same interest to increase knowledge in our field, train people to do a better job, increase visibility and strengthen our network.

Therefore, we will publish a series of contributions to IFAPP TODAY, about recent agreements: e.g., Memorandum of Understanding (MoU) and a link to it, a short presentation of the organisation, the goal of partnership, and the name and email of the person in IFAPP, which acts as the Point of Contact (PoC) for our members.

Organisation
As a first organisation, we herewith introduce PFMD (Patient-Focused Medicines Development, (https://patientfocusedmedicine.org) which is a
not-for-profit, independent global collaborative initiative benefiting patients and health stakeholders by designing a patient-centred healthcare system. It is managed by The Synergist (https:/www.thesynergist.org) and works to integrate the patients' voice across the entire medicines development lifecycle. Based in Brussels, Belgium, PFMD connects patient organisations, industry, and regulators to create a standardised, meaningful engagement through tools, resources, and training.

Goal of Collaboration
PFMD and IFAPP will cooperate and consult each other on matters of mutual interest, in particular those concerning patient engagement and Pharmaceutical Medicine, especially the development and testing of new pharmaceuticals and the ethical rules. They will agree and co-organise webinars or workshops in this regard and collaborate on joint articles to be published in their own media (such as IFAPP TODAY) or other journals.

Link to MoU

PoC:
Kotone Matsuyama (Japan); IFAPP President-elect
e-mail: m-kotone@nms.ac.jp

Author:
Robert Lins, MD, PhD, Specialist in Clinical Pharmacology and Pharmaceutical Medicine, Head of the IFAPP External Affairs Working Group (EAWG)

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Balancing Careers and Family Success in Pharma

Summary of the Webinar "Parenthood in Pharma: Strategies for Thriving before, during and after Leave" organised by the YPWG on March 17, 2026

On 17 March 2026, the Young Professionals Working Group (YPWG) hosted its latest webinar titled **"Parenthood in Pharma: Strategies for Thriving Before, During and After Leave."** The session was moderated by Alexandra Fritsche, Medical Affairs Scientist at Pfizer, and hosted Raoul Giger, Pricing and Market Access Manager at Sanofi Switzerland, as the guest speaker. Both the speaker and the moderator are parents of a young child, bringing a highly authentic and practical perspective to the discussion.

The webinar opened with a brief reflection on Raoul Giger's personal experience with paternity leave. His employer extended the statutory two weeks of paternity leave to 14 weeks, equivalent to the company's maternity leave policy, which he took in two separate blocks. He emphasised the importance of strong managerial and team support, which enabled him to fully disconnect during his leave. While he did not perceive a direct negative impact on his career, he noted a clear shift in priorities and a more conscious approach to how time and energy are allocated between work and family. His key message to young professionals considering parenthood was to move forward with confidence, seek open dialogue with their manager, and trust that workable solutions can be found.

> ***Key message #1:*** *Believe in yourself and approach parenthood with confidence. Don't hesitate to have open conversations with your manager about your needs and remember that together you can always find practical solutions. Your journey as a young professional can flourish with the right support and honest communication.*

The second part of the session focused on broader, structural questions around parenthood in the pharmaceutical industry. A central topic was how companies can better support employees to take parental leaves without facing career disadvantages. One key point was the importance of offering equal parental leaves for mothers and fathers, thereby normalising leave-taking across genders and reducing structural bias, particularly towards women. In addition, participants highlighted the role of public institutions in ensuring accessible and affordable childcare, which remains a significant barrier for many working parents.

At the organisational level, the discussion clearly showed that a supportive manager is often the single most critical factor in successfully balancing career and family. Despite progress, family responsibilities are still not consistently valued at senior leadership levels. Flexibility emerged as another essential enabler - allowing parents to temporarily disconnect during the day and compensate at other times, which helps accommodate unpredictable childcare needs, workloads, and deadlines.

> ***Key message #2:*** *To better support working parents, organisations should normalise equal parental leave for all genders, ensure access to affordable childcare, empower managers to actively support family needs, and provide flexible work arrangements that allow parents to balance unpredictable caregiving duties without career penalties.*

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Throughout the webinar, live poll questions were posed to the audience. Results showed that parental leave is widely perceived as a normal part of working life. However, the biggest concern remains to be potential career setbacks. Participants also identified unpredictable workloads, tight deadlines, and the feeling of needing to be "always available" as the most challenging aspects of balancing work and family.

Additional perspectives discussed included the importance of proactive planning before parental leave, transparent handovers, and structured return-to-work conversations to realign expectations. Mentorship, role models in leadership positions who openly combine career and family, and a company culture that measures performance by outcomes rather than presence were also identified as meaningful levers for change.

In conclusion, both the speakers and the moderator agreed that building a family while pursuing a career in pharma remains challenging. However, with the right preparation, supportive leadership, flexible working models, and an open team culture, it is possible to thrive in both domains. Despite the challenges, parenthood was described as deeply enriching and well worth the effort.

Key message #3: *Encourage proactive planning before parental leave, ensure transparent handovers and structured return-to-work discussions, promote role models who openly balance career and family, foster mentorship, and cultivate a culture that values outcomes over presence – so that employees can thrive in both parenthood and their careers.*

Author: Alexandra Fritsche, MD, Medical Affairs Scientist at Pfizer AG Switzerland

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Upcoming Young Professionals Working Group Webinar

During the next YPWG webinar "**Grow with the Experts! Level Up Your Career: The Mentorship Advantage**" on **14 May 2026**, 12:00-12:45 CEST, we will talk about mentorship programmes and why to participate in them. This webinar will provide practical insights: how to select the right opportunities, set clear expectations, build meaningful mentor-mentee relationships, and maximise the value of every interaction for long-term career development.

We invite you to join us over lunch as we examine the advantages and challenges of participating in mentorship programmes. Please have a look at the flyer below and register!

To register for the webinar, please click here

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

A Series of Discussions on the Revision of the WMA Declaration of Taipei on Health Databases and Biobanks: Facilitate Expanded Participation of Patients and the Global South

IFAPP's Commitment to the Ethics of Data-driven Research

The landscape of research and development (R&D) is undergoing drastic changes. Utilisation of real-world data (RWD), patient registries for medicines development have been formalised, and the use of artificial intelligence (AI) has been rapidly expanding both in R&D and clinical practice. Annex 2 (1), at the final phase of the ICH-GCP Renovation E6 (R3) (2), could establish guiding principles for considering the use of RWD in regulatory decision-making. International ethical and regulatory norms on AI and data governance have been enriched and are also expanding. At the same time, critical concerns have been raised regarding the cybersecurity risks on a massive scale and the issues of unequitable benefit sharing.

The World Medical Association (WMA) started the revision process of their Declaration of Taipei (DoT) (3) on health databases and biobanks (Table 1) in April 2025. In response, as IFAPP has a Memorandum of Understanding (MoU) with the WMA for mutual cooperation, we are hosting a series of webinars on "Ethics in Data-driven Research". The first webinar (May 2025) featured three leaders from the WMA (a report and a YouTube recording are available (4)). The second webinar (November 2025) featured a professor from National Taiwan University who is a member of the workgroup revising the DoT. Subsequently, in December 2025, the WMA's first open meeting was held in Taipei, Taiwan. In March 2026, the WMA's second meeting was held in São Paulo, Brazil. Also in March, the third IFAPP Webinar featured a Japanese patient group. Furthermore, on 25 May 2026, the fourth IFAPP Webinar will be held, focusing on the Global South, resource-limited settings, indigenous peoples and vulnerable patients.

This paper outlines the ongoing discussions. Furthermore, the WMA's regional meetings have been scheduled to take place on 1–2 June 2026 in Vatican City and on 14–16 September 2026 in Norway. Records of previous meetings and future schedules are available on the WMA website:
https://www.wma.net/what-we-do/medical-ethics/declaration-of-taipei/

Table 1 Points of the WMA Declaration of Taipei on Health Databases and Biobanks

The DoT covers "the collection, storage and use of identifiable data and biological material beyond the individual care of patients"; it provides the principles for:

- Privacy, confidentiality, security, etc.

It also requires developing a governance framework defining the policy for:

- Governance framework to inform the people who provide their data or biological materials.
- Returning of results including incidental findings.
- The rules of access to the Health Database or Biobank (HDB/BB).
- Commercial use, benefit sharing, intellectual property, material transfer agreement (MTA).
- Preventing discrimination.
- Considerations on change of ownership or closure of HDB/BB; etc.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The first WMA Meeting on the DoT, 4, 5 December 2025 in Taipei

At the opening ceremony of the meeting, the President of Taiwan, Dr Lai Ching-te, attended and celebrated the achievements of the President and Secretary General of the WMA. Just before the session on the DoT, in the morning of Day 1, the "International Symposium on Transforming Healthcare Universal Health Coverage, Artificial Intelligence, Green Healthcare and Collaborative Healthcare System" was held. WMA's Statement on AI (5) was introduced. Two important points of this Statement are (i) AI to use identifiable patient data must adhere to the DoT; (ii) patients have a right to request the removal of their own data from AI systems.

The history of the DoT was introduced, beginning in 1998 when a new Icelandic law was passed to authorise one private company to develop a genetic biobank of the whole Icelandic people. International medical communities expressed concerns, and the WMA provided a forum for discussion (6, 7). Then, the first Declaration on databases was adopted in 2002; it was revised in 2016 adding biobanks to its scope.

Issues of consent and governance framework, returning of results (RoR), de-identification and re-identification, etc., were extensively discussed. A younger doctor's search results utilising AI, found insufficiency of ethical considerations in the current DoT, reflecting recent technological innovations.

In the session on application of AI, a regulator in the Taiwan Ministry of Health and Welfare introduced the three centres for AI, including "Centre for External Validation", collaborating with Taiwan FDA (Food and Drug Administration). The European Union's AI Act (8) was introduced: the Act classifies the levels of categories of risk of being unacceptable; high; limited and minimal. The critical cases were discussed, e.g., AI inducing suicide; and Taiwan Human Rights Association's lawsuit seeking the removal of personal data from health databases. At the closing, the importance of respecting dignity, autonomy and privacy as well as of benefit sharing was stressed.

The second WMA Meeting on the DoT, 5, 6 March 2026 in Sao Paulo

At the second WMA meeting, it was noteworthy that the opening keynote speeches at the beginning of both days were provided by representatives of patient organisations: the World Patients Alliance (first day) and the International Alliance of Patient Organizations. AI use and the topics of privacy and governance were discussed among various interested parties.

Table 2 presents the discussion points in the WMA's meetings, consolidating my views from attending the two meetings (first one in-person, second one online).

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Table 2 Summary of the Discussion Points in the WMA's Open Meetings for the Revision of the DoT

Points about dignity, autonomy and privacy.

1. Development and use of **AI** is covered in the scope of the DoT; this means that AI use and development must adhere to the governance principles defined by the DoT.
2. Distinction between **individual-identifiable data** and **de-identified** data is almost impossible, especially in the situation of AI development/use.
3. Respect for **"Patients' right to consent"** is always stressed even in the situation of multiple, undefined uses of personal data. An "opt-out procedure" is not so much discussed nor recommended.
4. **"Broad (informed) consent"** to multiple uses based on information on expected future uses has been much discussed.
5. **"Dynamic consent"** to repeatedly shared information of the new projects of secondary data use based on continuing interactions with the participants is very important from the view of patients but not so much supported by speakers and panelists of the WMA's meetings.
6. Need for **"Returning research result"** was stressed very much by some of the speakers.

Points about governance, equitable benefit sharing

1. Need for **"governance"** has always been stressed by almost all speakers and panelists.
2. **"Equitable benefit sharing"**, especially in case of commercial use has been argued more by meeting participants rather than speaker/panelists.
3. **"Ownership"** has also been discussed but it was difficult to identify a clear description in principle due to the difference across regions.
4. **"Material transfer agreement"** was mentioned by South African participants as it was a critically important point proposed by the South African Medical Association (SAMA) in the previous revision in 2016. This point will be discussed in our next webinar.
5. **"Patient public involvement"** at all stages of establishment, use of HDBs and BBs: I pointed this out during my in-person participation as it is the most important item included in the last revision of the Declaration of Helsinki. But it has not been discussed much among the speakers/panelists.

IFAPP Webinar Part 3, 23 March 2026: Opinions from Patients and the Public on the DoT

Part 3 of the series of webinars on the WMA's DoT was held on 23 March 2026, with 118 registered participants of which 114 attended. The Japanese patient group, i.e., the Bioethics Working Group of the Japanese Institute for Public Engagement (Ji4pe), expressed their opinions. Their points are summarised in Table 3.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Table 3 Patients' Opinions on the DoT Expressed by Ji4pe Bioethics Working Group

1. Declaration described in **Plain Language**.
2. Respect for dignity of the **deceased person**; more in-depth consideration of the **human embryo** and **germ cells**, explicitly mentioning **AI**.
3. **Patients' and the Public's Involvement** in all stages of managing and the ethical review of health databases and/or biobanks (HDBs/BBs).
4. **Equitable Benefit Sharing** and **Prohibition of Exploitation**.
5. Outcomes from the use of HDBs/BBs as **Public Goods**.
6. Sustainable Development Goals (**SDGs**) and "**Gift**" for **Future Generations**.
7. Consent in the Age of Information Technology: **Broad Informed Consent**, **Dynamic Consent**, ensuring the **Right to Know and the Right Not to Know** in **Shared-Decision Making (SDM)**.
8. Participation of **Persons with Limited Capacity**.
9. **Social Consensus** Building and **Health Literacy** in the Digital Age.
10. Achievement of **Highest Global Ethical Standards**.

A paper authored by the Ji4pe Bioethics Working Group is available on the website of Clinical Evaluation: https://cont.o.oo7.jp/54_1/dot-ppi_en.pdf

Ji4pe was established by Dr Kyoko Imamura, a former President of IFAPP. She is also a former President of IFAPP's Japanese member association JAPhMed (Japanese Association of Pharmaceutical Medicine). This webinar is a collaboration between IFAPP and JAPhMed, and also between experts of Pharmaceutical Medicine and a group of patients and the public.
Before the presentation by the Bioethics Working Group, the author made a presentation to introduce the WMA's status of discussion towards the revision of the DoT, as mentioned above. In addition, one example of the Japanese project of patient registry was introduced. This project is a good example to establish the scheme for "dynamic consent", in the setting of "electronic patient-reported outcomes (e-PRO), which enables continuing interactions with registered patients. It also enables patient public involvement at all stages of HDBs/BBs.

Following expressions of patient opinions, global discussions were formed with active participations of IFAPP members, academic researchers/bioethicists and patients.

IFAPP Webinar Part 4, 25 May 2026: Perspectives of Global South, Resource-limited regions, Indigenous People and Vulnerable Patients
The next webinar on the DoT is a collaboration among the global network that has been continuously discussing global ethical norms such as the WMA Declaration of Helsinki (DoH) and then the DoT. Some of the speakers are in-person participants of the WMA's meeting in Taipei in December 2025, who expressed concerns from the view of indigenous people.
The webinar will be supported by the Philippine Medical Association, the Philippine College of Pharmaceutical Medicine (PCPM, IFAPP's National Member Association: NMA); the Japanese Association of Pharmaceutical Medicine (JAPhMed, also IFAPP's NMA) the Japanese Institute for Public Engagement (Ji4pe); and the Brazilian Society of Bioethics.

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

The time frame, the registration information and a part of the leaflet are presented below. More details can be found via the link to the original leaflet. We look forward to discussions with IFAPP friends at the webinar!

Date and Time Frame:
25 May 2026, Monday 3 hours: 13:00- CEST, SA / 14:00-Greece /
20:00- JST /19:00- Philippine / 8:00- Brazil, Argentina / 7:00- EDT
Free registration via the link or QR Code
https://forms.gle/t9d9BRqQ4tTwuiCc8

Part of the leaflet: More details including titles of presentations are available under
https://cont.o.oo7.jp/sympo/260525.pdf

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

References

(1) International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline: Guideline for Good Clinical Practice E6(R3) Annex 2. Draft version. Endorsed on 6 November 2024. Currently under public consultation.

(2) International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline: Guideline for Good Clinical Practice E6(R3). Final version adopted on 6 January 2025.

(3) World Medical Association. WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks. First adopted October 2002, revised October 2016.

(4) Lehmann B, Kurihara C. Summary of the Webinar of 6 May 2025: Ethics in Data-driven Research: WMA Declaration of Taipei on Health Databases and Biobanks Part 1: Introduction and future direction. IFAPP TODAY. 2021; No. 55: 8-11.

(5) World Medical Association. WMA Statement on Artificial and Augmented Intelligence in Medical Care. Oct 2025.

(6) Snaedal J. Interviewed by Kurihara C, Saio T. Interview with Dr. Jon Snaedal, Chair of the World Medical Association Workgroup for the Taipei Declaration; Representative of the Icelandic Medical Association: Health databases, biobank and fundamental human rights. Rinsho Hyoka (Clinical Evaluation). 2018; 46(1): 165-70. h

(7) Matsuyama K, Kurihara C, Crawley FP, Kerpel-Fronius S. Utilization of genetic information for medicines development and equitable benefit sharing. Front Genet. 2023 Jun 14;14:1085864.

(8) Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act). PE/24/2024/REV/1. OJ L, 2024/1689, 12.7.2024.

Author:
Chieko Kurihara, Specially-appointed Professor, Kanagawa Dental University, Editor-in-Chief, Clinical Evaluation, Member of Bioethics Working Group of Ji4pe, Japan

IFAPP TODAY
The Global Pharmaceutical Medicine Journal

Free Webinar: "Are We Running out of Antimicrobials?", 26 May 2026, 12.00 noon CEST

Antimicrobial resistance (AMR) is increasingly challenging modern medicine and raising a pressing question: are we approaching a post-antibiotic era? This webinar examines the current situation in Switzerland and internationally, focusing on what happens when no effective antibiotic is available for a patient. We will explore how often such situations occur, which pathogens are most concerning, and which patient populations are particularly at risk (especially critically ill patients in intensive care units; ICUs), as well as vulnerable groups in more general clinical settings. The discussion will address multidrug-resistant organisms, treatment limitations, clinical outcomes, and the real-world consequences for patient safety, hospital workflows, and healthcare systems.

Speaker: Professor Dr Silvio Daniel Brugger, FESCMID

Prof Silvio Brugger is a Senior Attending Physician and Head of the Clinical Microbiology Laboratory (Hospital Epidemiology Laboratory) in the Department of Infectious Diseases and Hospital Epidemiology at the University Hospital Zurich, Switzerland. He is also a Professor at the University of Zurich holding an SNSF (1) Starting Grant. He teaches at the ETH (2) and the University of Zurich.
As a Fellow of the European Society of Clinical Microbiology and Infectious Diseases (FESCMID), Professor Brugger serves on ESCMID's Executive Committee and the Swiss Society for Infectious Diseases as well as the ESCMID guideline committee. He holds Swiss Board Certifications in Internal Medicine and Infectious Diseases, with a focus on AMR, microbiota and bacterial colonisation.

After completing Switzerland's national MD-PhD programme, Professor Brugger pursued postdoctoral research at Harvard Medical School in Cambridge, USA. His work has earned multiple awards, including the Siegenthaler (3) and SGM (4) Awards, and he completed his habilitation at the University of Zurich in 2021. Professor Brugger's research emphasises microbiota-targeted strategies to combat AMR and his clinical expertise focuses on multidrug-resistant (MDR) infections.

Click here to register for this webinar

Abbreviations:
(1) SNSF: Swiss National Science Foundation
(2) ETH: Eidgenoessische Technische Hochschule (Federal Institute of Technology) Zurich
(3) Siegenthaler award is a prestigious award given by the Walter and Gertrud Siegenthaler Foundation to outstanding young researchers in the field of medicine
4) SGM Swiss Society for Microbiology

IFAPP TODAY

The Global Pharmaceutical Medicine Journal

Upcoming Free Webinars

- 15 April 2026 - New Provisions in the pharma legislation: will they solve the future challenges concerning pharmaceuticals.
  Click here to register.
- 14 May 2026 - Live-Meeting Series “Grow with the Experts!”
  Click here to register
- 25 May 2026 - Perspectives of Global South, Resource-limited regions, Indigenous People and Vulnerable Patients
  Click here to register.
- 26 May 2026 - Are We Running out of Antimicrobials?
  Click here to register.

THE FLAG

IFAPP Secretariat - Leidsestraatweg 41d - 3443 BP Woerden - The Netherlands
Chamber of Commerce 30224375 – VAT number NL817747321B02
Phone: (+31) 6 2291 1039 – e-mail: secretariat@ifapp.org – website: www.ifapp.org

IFAPP Communication Working Group
Ghazaleh Gouya-Lechner (Chair), Assem el Baghdady, Varvara Baroutsou, Francesco Butti, Brigitte Franke-Bray (Editor), Anna Jurczynska, Rita Lobatto, Kotone Matsuyama and Yasmin Nagaty (Editor).

Production and layout
Caroline van Bruggen and Manon van Galen

IFAPP is the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.

Follow us on: