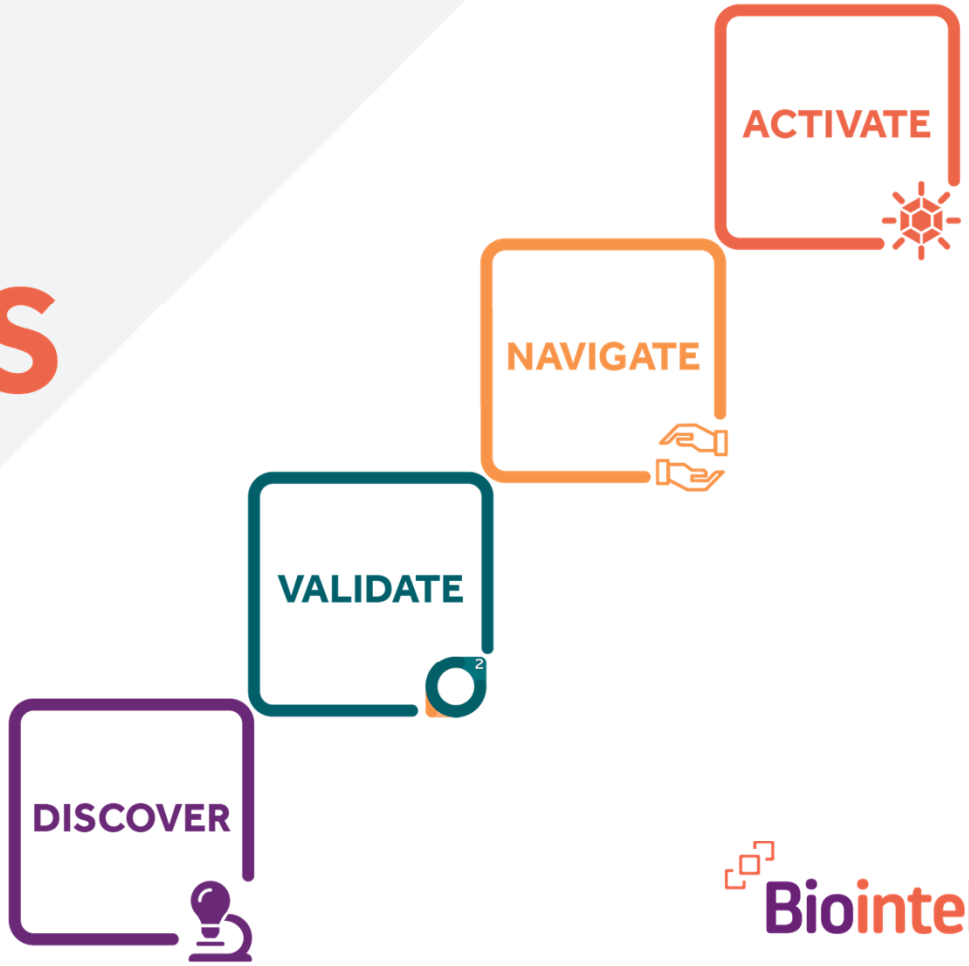
BRINGING INNOVATIONS TO LIFE

STEP BY STEP



Biointelect

Bring your innovations to life

Biointelect is with you every step of the way, providing the deep expertise to ensure your life science innovation is ready for successful commercialisation.

DISCOVER

Leverage our expertise and strategic project management to **refine your innovative ideas** into actionable and successful commercial projects.

VALIDATE

Lay the essential foundations for commercial success by drawing on **our knowledge of the life science ecosystem, regulatory and clinical pathways**.

NAVIGATE

Navigate the challenges of bringing a therapy to market leveraging our **broad cross-functional experience.** Build vital knowledge to inform **all stages of market readiness**.

ACTIVATE

Secure your innovation's long-term commercial viability as a successful resource that supports **healthcare professionals and patients in need**.

Discover

Leverage our expertise and strategic project management to refine your innovative ideas into actionable and successful commercial projects.

- Collaborate with our team to prioritise and develop a clear, compelling value proposition that sets your innovation apart in the market
- Create a strong business case and funding proposals that secure the resources needed to drive your project forward
- Benefit from our Strategic Project Management services to streamline the entire product development process and optimise your path to market

Research & Development Strategy and Planning | Grant Funding and Business Case Proposals | Portfolio Prioritisation | Target Product Profile Development

Research & Development Strategy & Planning

Research & Development Strategy & Planning

We support you to navigate, de-risk and accelerate the complex journey from benchtop research to successful commercialisation by offering integrated and tailored support in portfolio prioritisation, preclinical, clinical, commercial, regulatory, funding strategy, and strategic program management.

- **Strategic Project Management** – Starting with the end in mind, Biointelect can streamline your path to market through strategic expertise and tailored planning to drive each stage of the product development journey towards an impactful outcome.
- **Scientific Affairs** – Offering expert support in scientific communications and writing, commercialisation planning, and funding strategy to facilitate the seamless translation of discoveries into practical applications.
- **Funding Strategy Support** – Throughout the R&D journey, Biointelect helps devise funding strategies, whether dilutive or non-dilutive. From crafting commercialisation business cases to positioning value propositions for investor pitch decks, we empower clients to confidently plan for their next phase.

- ✓ Product development plans
- ✓ Commercialisation business cases for grants
- ✓ TPP workshops
- ✓ Scientific communication support (writing of white papers, publications, grants)
- ✓ Commercialisation workshops
- ✓ Strategic Project Management through preclinical and clinical development

Validate

Lay the essential foundations for commercial success by drawing on our knowledge of the life science ecosystem, regulatory and clinical pathways.

- Understand your potential with our comprehensive market analysis services and take the first steps towards commercialisation with our business insights
- Prepare the pathway forward with a regulatory roadmap and robust clinical development strategies
- Generate a strategic trial design, and conduct the trials to ensure robust clinical outcomes that reflect the full potential of your asset
- Establish a local presence to capitalise on research and development incentives with our Director Services to register an Australian corporate entity and appoint an ASIC-approved, Australian resident company director to oversee local clinical development initiatives

Market Analysis and Business Insights | Director Services | Clinical Development Strategy | Clinical Trial Execution | Full Service CRO Services | Regulatory Strategy

Director Services

Director Services

We streamline your entry into Australia's R&D landscape by providing tailored solutions for subsidiary establishment, strategic project management, and access to a diverse partner network, enabling best strategic choices and partnership opportunities.

- **Resident Director** – Accredited directors with sector-specific expertise to ensure corporate governance and other business registration requirements are met, as well as to add strategic value.
- **Corporate** – Take on the role of Company Secretary or will utilise our extensive industry network to recommend an experienced local partner.
- **R&D Tax Incentive (RDTI)** – Work with preferred experienced local partners to leverage the Australian targeted tax offset program.
- **Financial Accounting** – Ensure all financial reporting requirements with the Australian Tax Office (ATO) are met according to timelines.

- ✓ Co-ordinate Australian company establishment
- ✓ Offer Australian registered office services
- ✓ Advise and assist with documentation required to lodge an eligible R&D Tax offset
- ✓ Prepare board papers and minutes, annual corporate secretarial reports, and maintain company records
- ✓ Manage company financial accounting requirements per ATO legislation

Clinical Research Services

Conducting your clinical trials in Australia allows you to leverage the benefits of the Australian clinical research environment to conduct your study with faster start-up timelines, efficient regulatory and ethics assessment, and attractive tax incentives.

Clinical Research Services

Our team has extensive experience in Phase I to IV clinical trial oversight across a range of therapeutic areas, including vaccines, infectious diseases, oncology, neurology, dermatology and immunology.

- **Clinical Trial Management** – Support you from trial synopsis and protocol development up to finalisation of the clinical report.
- **Medical and Scientific Writing** – Transform complex ideas into concise documents essential to publish reliable research data.
- **Data Management** – Turn your data into knowledge using state-of-the-art Electronic Data Capturing Systems.
- **Biostatistics** – Analyse, interpret and present your data, ensuring traceability, reproductivity and compatibility across studies.
- **Safety Management and Medical Monitoring** – Ensure safety is properly managed throughout the lifecycle of your program.

- ✓ Strategic Project Management through preclinical and clinical development
- ✓ Clinical strategy and trial planning
- ✓ Clinical trial feasibility assessments
- ✓ Clinical trial execution with full-service CRO capabilities
- ✓ KOL stakeholder mapping and site identification
- ✓ Vendor selection and liaison
- ✓ Quality and compliance advisory
- ✓ Clinical study protocols and reports
- ✓ Investigator brochures
- ✓ Scientific publications

CRO Services

Biointelect offers the full range of clinical research services that can be tailored to meet your needs.

Study Management

- ✓ Project Management and oversight.
- ✓ Ethics and regulatory submissions.
- ✓ Vendor management (IP, central laboratories).
- ✓ Trial Master File setup, maintenance, quality assurance and close-out.
- ✓ Site and Sponsor communications.
- ✓ Regular operations meetings/teleconferences with sponsor.
- ✓ Risk Management.

Clinical Monitoring

- ✓ Plan development (Monitoring Plan).
- ✓ Initiation, monitoring (onsite and remote), Close-out.
- ✓ Site communication.
- ✓ Protocol deviation surveillance and reporting.

Design and Review of Oversight Plans

- ✓ DSMB/SRC charter.
- ✓ Design of plans including; Project Management (including communication and risk) monitoring, Safety Management, Data Management, and Statistical Analysis Plan.

Medical and Safety Monitoring and Pharmacovigilance

- ✓ 24/7 local oversight medical monitoring, DSMB management including report preparation and meeting/s, review and approve medical narratives.
- ✓ Register the therapy in the appropriate databases and prepare/submit SUSAR submission to TGA.
- ✓ Draft interim and annual safety report, if/as required

Data Management, Biostatistics, and Medical Writing

- ✓ Electronic data capture (eDC) - develop eCRF and completion guidelines, train the site, data monitoring and coding, perform EDC computer system validation.
- ✓ Draft statistical analysis plan, perform interim and final statistical analysis, provide TLF and final statistical report.
- ✓ Preparation of Clinical Study Report.

Investigator Site Oversight

- ✓ Ethics and Site-Specific Application. JW0
- ✓ Participant recruitment, clinical and medical oversight of participants.
- ✓ Conduct of clinical trial procedures per protocol, collection, and processing of biological samples.
- ✓ Pharmacy services.
- ✓ Data entry into eDC, maintenance of investigator site file.
- ✓ Local laboratory testing (if required).

Slide 8

JW0 What does this mean? We don't actually do the recruitment, pharmacy services, data entry, etc.
Jacqui Wade, 2024-09-19T22:51:10.113

KG0 0 I re-worded the title so its clear its our oversight of the site
Kara Gooley, 2024-09-19T22:56:21.517

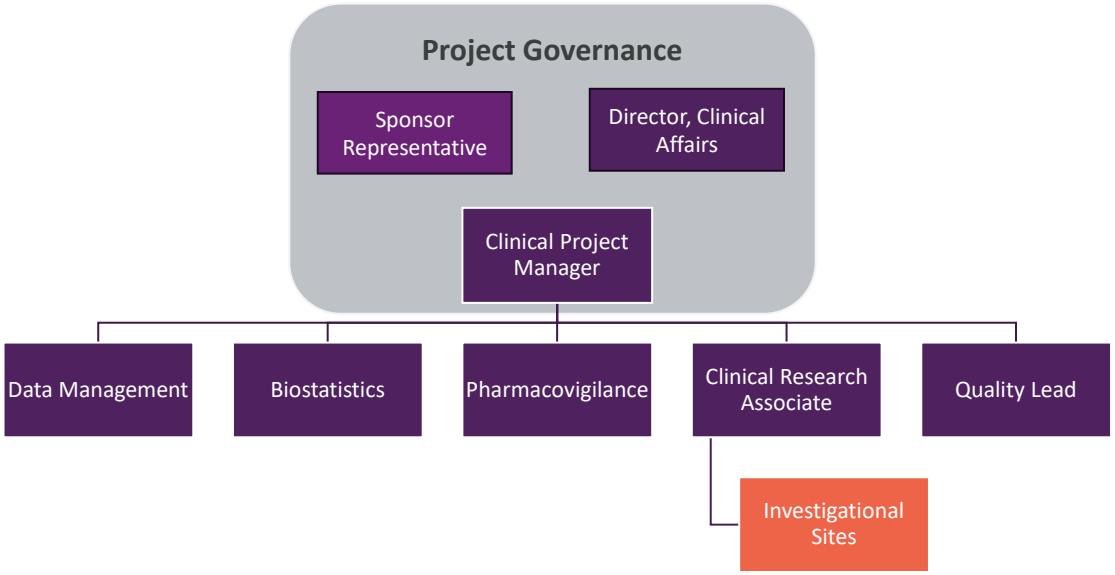
Project Delivery

Biointelect works seamlessly with you to ensure successful delivery of clinical trials. Our vision, mission and core values provides our clients with the sense of unity and drive towards achieving shared outcomes.

Consistent Delivery
Standard Operating Procedures ensuring consistent project delivery.

Key Systems
e-TMF platform to manage clinical trial documentation.
Quality Management System for managing controlled documents.
Salesforce for full financial oversight of the project.

Governance
An experienced project manager will be the central contact person and work closely with the Director, Clinical Affairs. Every project is reviewed biweekly by senior management.



Quality and Compliance

Compliant every step of the way within GxP. All Biointelect's clinical vendors and subcontractors are qualified suppliers.

We follow all applicable regulations:

- ✓ ICH Good Clinical Practice (GCP)
- ✓ Good Laboratory Practice (GLP)
- ✓ Good Manufacturing Practice (GMP)
- ✓ ISO9001 standards (Quality management systems)

- ✓ FDA Clinical Trial Regulations
- ✓ US Health Insurance Portability and Accountability Act (HIPAA)

- ✓ Clinical Trials - National Standard operating Procedure for Clinical Trials, including Teletrials in Australia based on ICH E6 (R2)
- ✓ Australian Clinical Trial Handbook - Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods Version 2.4, August 2021
- ✓ The National Statement on Ethical Conduct in Human Research (2023)

- ✓ Medicines Australia Code of Conduct
- ✓ British Pharmaceutical Industry Code
- ✓ Legal and country-specific regulations

Transcending Geographical Boundaries

Biointelect's and CR2O's strategic partnership harnesses the market contextual knowledge and ground support, expanding your clinical trial horizons across Australia and the European Union, and delivering fit-for-purpose clinical development solutions to patients faster.

Extensive Trial Experience
A decade record of complex clinical development programs and implementing phase I-IV clinical trials, our team has expertise across a large diversity of therapeutic areas including vaccines, infectious diseases, oncology, neurology, dermatology and immunology.

Global Network
Biointelect's and CR2O's global ecosystem integrates end-2-end expertise to advance new therapies from bench to bedside.

Cross Functional Services
The combined services of our different cross-functional experts accelerate product development planning. Our Non-Clinical, Clinical, CMC and Regulatory experts all have hands-on experience, capable of meeting your specific needs.

Strong Clinical Track Record
CR2O have a strong track record having conducted studies at over 150 research sites for 26 indications with trials from Phase 1 through Phase 4 across 6 continents. Recent international projects with strong societal impact include two CEPI funded Phase I and Phase II studies for Rift Valley Fever and MERS Coronavirus (CR2O sponsor and co-developer, respectively), and two Horizon2020 funded programs targeting SARS-CoV-2 and influenza (CR2O sponsor and consortium member, respectively).

Biointelect

Regulatory Strategy

We complement your regulatory team capabilities by offering integrated regulatory guidance and recommendations across all stages of the development cycle.

Early stage

- Identifying the regulatory requirements and strategy early on reduces the risk of delays in late-stage development.

- ✓ Alignment of business objectives with regulatory requirements
- ✓ Product development roadmap
- ✓ Regulatory Advice (TPP, ad hoc, workshops)
- ✓ Gap Analysis of safety data for FIH studies
- ✓ IB, IMPD, IND and CTA preparation

Growth stage

- Implementing a well-defined go-to-market regulatory strategy, while keeping track of ever-changing global regulations and company requirements is a key to commercial success.

- ✓ Go-to-market regulatory strategy
- ✓ Pre-submission meetings and briefing book preparation
- ✓ Provisional, Priority and Orphan Designation applications
- ✓ CTD gap analysis & remediation plans
- ✓ Full ANZ registration applications
- ✓ Due diligence for M&A activities

Late stage

- In addition to serving as a liaison with regulatory agencies for submissions and approvals we also provide establishment of a post-approval quality and regulatory framework.

- ✓ APAC regional expansion strategy
- ✓ Post approval regulatory strategy, compliance and agency engagement
- ✓ Lifecycle management with Biocelect as local ANZ Sponsor (Registration holder)
- ✓ Evaluate emerging issues and trends for regulatory impact

Navigate

Navigate the challenges of bringing a therapy to market leveraging our broad cross-functional experience. Build vital knowledge to inform all stages of market readiness.

- Work with our functional experts to develop a commercial strategy that optimises market positioning and maximises impact and value
- Achieve your regulatory goals; our global network and deep expertise in regulatory pathways inspires our tailored solutions across strategic planning, implementation, and direct engagement with regulatory agencies to ensure compliance and accelerate market entry
- Capitalise on our diverse leadership experience in HTA to strategically prepare your submission
- Undertake financial and economic modelling with data analysis to support corporate and product commercialisation strategy

Regulatory Submissions | HTA Assessment | Economic Assessment | Commercialisation Strategy

Commercialisation Strategy

Commercialisation Strategy

We provide you with strategic commercial and regulatory insights for all major markets, links to global networks, access to pre-clinical and clinical experts, ensure investor readiness with a tailored approach to navigate the complexities of the industry. This gives you the best chance of swift and impactful commercialisation.

- **Business and Marketing Plans** – Empower your decision-makers with actionable insights that can drive growth, enhance efficiency, and fortify your competitive edge.
- **New Product Commercialisation** – Cross-functional solutions drawing in Biointelect's expertise across market access, medical affairs, commercial, regulatory services, health economics and policy.
- **Market and Competitive Landscape Assessment** – Insights and expertise that empower you to make informed decisions, seize opportunities, and strengthen your positioning in a rapidly evolving market.
- **Financial and Health Economic Modelling** – Tailored to support and guide your strategic decisions based on your product development plans and overarching goals.

- ✓ Market assessments across all major markets
- ✓ New product plans
- ✓ Product development plans
- ✓ Funding strategies, including grants
- ✓ Patient journey mapping
- ✓ Stakeholder/ KOL mapping and engagement
- ✓ Investor pitch decks
- ✓ Market positioning strategy

Activate

Secure your innovation's long-term commercial viability as a successful resource that supports healthcare professionals and patients in need.

- Our team of public policy analysts and health economists offer leadership in market shaping
- Leverage our innovative thinking in health and life sciences infrastructure, including the design of public-private partnerships and strategic planning for major projects
- Establish category thought leadership with our White Paper development and publishing
- Optimise return on investment with robust pricing strategy and comprehensive life cycle management
- Deep industry expertise makes us an ideal go-to partner for non-industry partners seeking engagements

New Product Planning | Policy Shaping | White Papers | Lifecycle Management

Patient Access and Health Economics

- ✓ Australian and international market access and reimbursement strategy
- ✓ Evidence review, gap analysis and reimbursement submission expertise
- ✓ Patient journey mapping
- ✓ Stakeholder mapping and engagement
- ✓ KOL/stakeholder advisory boards
- ✓ Health economic analyses & evaluation
- ✓ Primary health economic research
- ✓ RWE strategy and planning
- ✓ Policy white papers, submissions and roundtables

Patient Access & Health Economics

We support you to accelerate patient access to innovation by optimising reimbursement outcomes with cross-portfolio and product strategies, navigating complex environments for first-to-market technologies, finding common ground with stakeholders to shape policy and developing practical and resource-efficient data strategies.

- **Market access and Reimbursement Strategy** – Optimise reimbursement outcomes with cross-portfolio and product strategies.
- **Health Economics and Health Technology Assessment** – Bespoke health economics and HTA solutions at your stage of product development.
- **Data Strategy and Real World Evidence (RWE) Generation** – A personalised strategy to enable you to generate the evidence you need for your product.
- **External Stakeholder Engagement and Policy** – Meaningful interactions with external stakeholders through trust and leadership in the health and life sciences sectors.

Government and Policy Services

Government Services & Policy

- ✓ Strategic business case development
- ✓ Business plan development
- ✓ Ecosystem mapping, policy review and development
- ✓ Public health and pandemic preparedness leadership
- ✓ Navigating the emerging and complex medicine landscape (e.g., genomics and precision medicine)

We provide you guidance by offering a unique understanding of the intersection between the elements of the innovation environment and strategic planning in the healthcare sector to advise on major infrastructure projects and policy reforms that will benefit health outcomes for all Australians

- **Health and Life Sciences Infrastructure and Precincts** – Leadership, strategic advisory services and project management to support major investments.
- **GMP on manufacturing advice and project management** – Experience in business planning through guidance on design and build, and partnership to enable OGTR and/or TGA success in engagement.
- **Public Policy and Business Case Development** – Policy analysis and evaluation across the health and life sciences sectors.
- **Public Health and Pandemic Preparedness** – Leadership in critical areas affecting public health and national security.

Strategic Project Management

Biointelect simplifies project management so clients can focus on core R&D.

Experienced Project Managers
Broad experience with diverse clients: University/MRI/Startups, to NGOs, and government organisations to large multinationals.

Beyond Classical Project Management
Providing team and vison management in combination with strategic thinking and project intelligence.

Path to Market Expertise
Fastest, most cost-effective market paths for biopharma products.

Helping you Function as a Team
Streamlining communication for consistent messaging and focusing teams towards joint successful outcomes.

Strategic Knowledge Integration
Combining business strategy with project management. Specialist expertise in commercialisation, regulatory, and reimbursement. Local and international market knowledge.

A proven track record

Since 2012, we have completed over 500 projects for 170 clients across various therapeutic areas and geographies with a focus on a broad range of advanced and emerging technologies

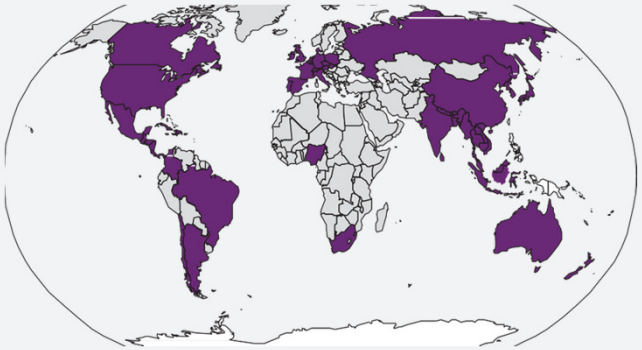
Technologies & Product Type Examples

- Vaccines & Infectious diseases
- Cell & Gene Therapies
- Precision Medicine & Diagnostics
- Clinical Trials
- Radiopharmaceuticals
- Genomics

Comprehensive disease area expertise

- Oncology
- Rare Disease
- Cardiovascular & Metabolic
- Neuroscience
- Other

Projects conducted across >40 countries



The Biointelect difference: giving you confidence in your goals

Our deep expertise across the full life science value chain delivers a high-quality tailored partnership enabling you to meet strategic goals and ensure success of your full innovation journey to commercialisation.

Deep Knowledge of Life Science Ecosystem

- Our comprehensive understanding ensures we navigate complexities effectively.

Local and Global Reach

- We leverage our extensive network to provide global insights with local relevance.

Strategic Advice and Technical Support

- Tailored solutions and insights drive confident decision-making.

Experience from Research to Commercialisation

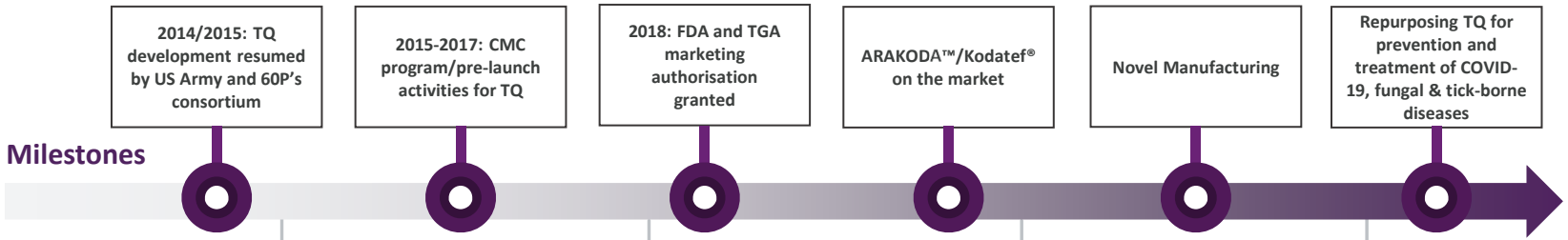
- We support the entire innovation journey with proven expertise.

Quality of Our Network

- Our connections facilitate valuable partnerships and opportunities.

Case Study: Full Value Chain Services to bring novel antimalarial to market

- 60 Degree Pharmaceuticals (60P) employed a virtual model of drug development and worked for 4 years with a consortium of US and Australian based service providers including Biointelect to gain regulatory approval by the US Food and Drug Administration (FDA) and Australian Therapeutic Goods Administration (TGA) and launch Tafenoquine (TQ) onto the US and Australian market.



Biointelect's services

Regulatory Support

- Completed CMC program developed in less than 2 years;
- Review of regulatory requirements, gap analysis to address the preclinical and clinical gaps in dossier, prior phase III trials were completed for TQ capsules;
- Additional trials conducted to provide necessary clinical information;
- More than 150,000 pages of regulatory documents were compiled and submitted to the regulators.

Medical Affairs

- Mapping of 400 malaria experts & travel medicine clinicians in top 20 markets;
- Mapping of policy decision making and stakeholder organizations in malaria;
- Global TQ advisory board in Barcelona in 2017;
- Workshops and educational activities to support clinical trial recruitment and incorporation of G6PD testing in routine practice;
- KOL engagement, conferences, meetings.

R&D Project Management

- Australian resident Director services for 60 Degrees Australia Pty Ltd;
- R&D tax credit – support for Aus Industry applications;
- Sourcing and coordination of legal, financial and accounting providers;
- Assistance with grant applications;
- Ad hoc strategic support to 60P Board as required.

Commercial Strategy

- Global forecast for TQ including pricing and reimbursement;
- Market research into travel medicine, business model and impact of G6PD testing requirement for TQ in Canada, US, UK, France.

Outcomes & Future development

TQ was the first prophylactic antimalarial drug approved by FDA and TGA in almost two decades.

- FDA and TGA regulatory approvals granted in August and September 2018 respectively

TQ approval for malaria prophylaxis is a milestone, but not the finish line.

- TQ is well-suited for addressing important public health issues such as its use in children and eliminating malaria transmission on Asian and African islands.

60P has partnered with Defence Material Technology Centre (DMTC) to develop a novel manufacturing method for TQ, using flow chemistry.

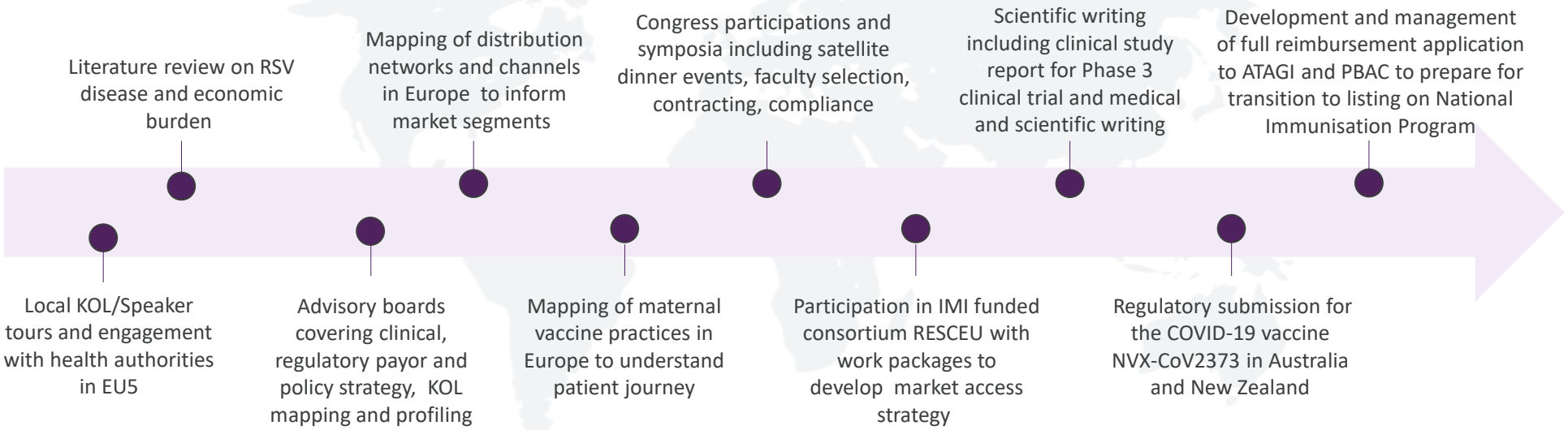
Case Study: Full Market Access & Economic Modelling Support for Global Biopharma

- Biointelect is supporting a global biopharmaceutical company with market access activities for the launch of their novel gene therapy treatment for a rare immunological disease into the Australian market

Biointelect developed a **robust submission strategy**, leveraging insights from advisory boards and the Australian clinical landscape. Through **targeted KOL engagement** and **strategic market shaping**, we've laid essential groundwork for **launch readiness**. Our cost-effective **PBAC submission** preparation and on-the-ground expertise demonstrate our adaptability and long-term commitment as a **strategic partner**, positioning the client for future success in the Australian market.

Case Study: Comprehensive Affiliate Partnership Model for vaccine in ANZ

Biointelect have supported Novavax since 2014 (phase 1) with ex US medical affairs, policy, market access and commercial strategy for their vaccine pipelines. We have supported all aspects of local KOL and stakeholder engagement, government relations, health economics, policy and communications including acting as representative with the TGA and Department of Health, attending high level events such as policy forum, key scientific meetings, coordinating advisory boards and all management activities for a submission to ATAGI and the PBAC for future listing on the National Immunisation Program.



Biointelect's added value:

- Local knowledge and experience has enabled Biointelect to navigate the Australian and New Zealand regulatory and reimbursement systems and provide regulatory and reimubursement submission support for the client.

LG0

Slide 23

LG0 Would we add to this now with the PBAC and ATAGI submissions we have done / are doing?
Leah Goodman, 2024-09-03T00:23:31.137

NS0 0 [@Danijela Mirosa] your thoughts on this comment
Nicole Sidwell, 2024-09-05T23:07:13.955

DM0 1 Yes definitely needs to be added - let me take a look
Danijela Mirosa, 2024-09-05T23:36:39.026

DM0 2 [@Nicole Sidwell] and [@Leah Goodman] completed - updated with ATAGI and PBAC
Danijela Mirosa, 2024-09-06T00:46:02.123

Key Contacts

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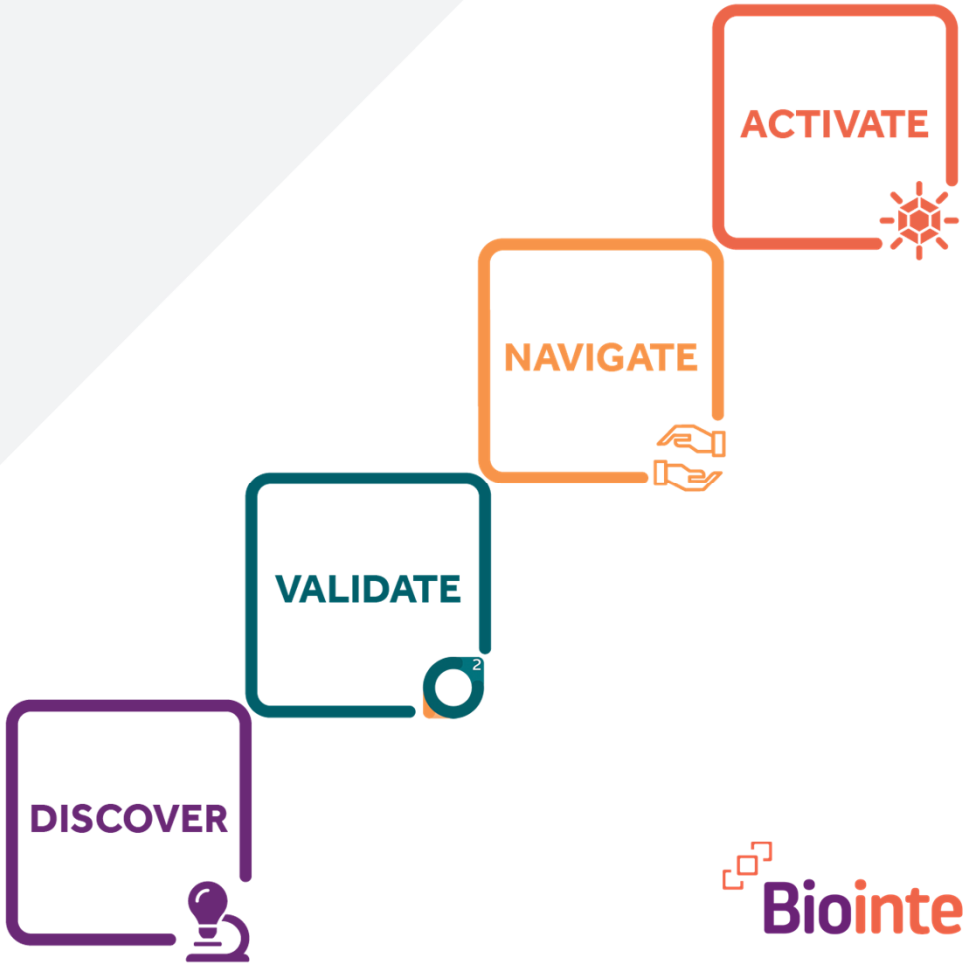
BRINGING INNOVATIONS TO LIFE

STEP BY STEP

Selected Team Profiles

Meet the full team on the website.



Biointelect

https://www.biointelect.com/company/our-people/

Leah Goodman

Chief Executive Officer

Leah Goodman joined as Chief Executive Officer after over 5 years as Managing Director ANZ with Bristol-Myers Squibb and Merck Healthcare. Prior to this Leah spent 15 years with Sanofi with commercial Regional responsibilities including Japan, South Korea, Australia/New Zealand as Vice President based in Tokyo, and South-East Asian countries as Managing Director based in Malaysia.

Through her Industry Association Board leadership across Asia and Australia Leah has played a significant role in market shaping for equitable healthcare access, including as a member of the Board of Medicines Australia from October 2019 to December 2021. Her experience spans innovative biotechnologies across diverse therapeutic areas, including immunooncology, rare diseases, cell and gene therapies, immunotherapies, neurology, diabetes, cardiovascular, fertility, primary care and OTC medicines. Leah also has a depth of experience across government investment into infrastructure with cell and gene therapy manufacturing in RNA and Viral vectors. Leah has a Bachelor of Science and Masters of Commerce from UNSW, is an AICD Graduate, and has certification in advanced GMP manufacturing.

Today, Leah is active in the Australian Life Science network, participating as a member of the AusBiotech NSW Leadership Committee, and as a member of the Catalyst Cell and Gene Therapy Policy and Advocacy Working group. She is a member of the Australian Chief Executive Women Network and is an actively passionate advocate for diversity.

Jennifer Herz

Co-founder and Director

Jennifer Herz, GAICD, co-founded Biointelect in 2011, offering end-to-end strategic commercialisation services to the biopharmaceutical sector. She has over 30 years of experience in commercial, business development and scientific affairs within the biopharmaceutical industry across Australia, New Zealand and Europe.

Early in her career, she played a pivotal role at Sanofi Pasteur, establishing and managing the company as a major provider of vaccines in Australasia. She was also the founding Chair of the Medicines Australia Vaccine Industry Group and has extensive Board experience, serving for publicly listed private and not-for-profit organisations, including Medicines Australia. She then took on a regional policy and market access role where she was engaged in various international industry association working groups, fostering relationships with health authorities, the EU institutions, and the WHO.

More recently, Jennifer took on Director roles in two NASDAQ-listed US-based biotech company subsidiaries in Australia, became a member of influential committees like the NHMRC's Health Research Impact Committee, the NSW Innovation and Productivity Council, and the Australian AMR Network's steering committee.

During her time leading Biointelect, she has overseen more than 450 projects, providing rich and diverse experience in the complexity of life science product development and integrated commercial strategy. This experience includes successful FDA, EMA and TGA approvals, global launches, and product and company failures, providing valuable learning opportunities.

Jennifer has an extensive local and international network of industry, policy, scientific and clinical experts across many therapeutic areas and healthcare sectors, along with global experience in multiple new product launches and start-ups at all stages of development.

Jacqui Wade

Director, Clinical Affairs and Director Services

Jacqui Wade brings over 30 years of expertise in the pharmaceutical and biotech sectors, holding a Bachelor of Science degree with majors in Pharmacology and Physiology. Her career spans clinical research and product commercialisation across various therapeutic areas, including oncology, neuroscience, HIV, immunology, and infectious diseases, working for multinational corporations, small biotech, and a Clinical Research Organisation (CRO).

Early in her career, Jacqui played a pivotal role in establishing a Phase I clinical trial unit at a generics company. Later, at Janssen and Pfizer, she managed Phase II–IV clinical trials for conditions like schizophrenia, dementia, infectious diseases and solid and haematological cancers. She then transitioned into commercial roles, excelling in New Product Commercialisation and in-line marketing. She successfully led PBS launches for pioneering therapies targeting prostate cancer and chronic lymphocytic leukaemia. More recently, Jacqui served as a Project Director at a CRO, overseeing Phase I-II clinical trials and supporting small to medium-sized biotech clients. She also held the position of Director, Business and Clinical Development at a small biotech company.

Jacqui joined Biointelect in 2022, contributing her strategic mindset and project management skills to projects involving product development pathways and supporting businesses. Recently, Jacqui assessed an organisation's market position, identified future opportunities, and developed action plans for commercial success. Her career reflects a wealth of experience and a strong track record in the life sciences industry.

Kara Gooley

Senior Clinical Project Manager

Kara brings over 23 years of clinical research experience in the pharmaceutical and clinical research organisation sector. She holds a Master of Medical Science, Drug Development from the UNSW and a Bachelor of Science with a Biological Science major from Macquarie University. Her career has spanned Phase I (including First Time in Human (FTIH)) to Phase IV trials with the last 15 years focused on early phase research (FTIH to Phase 2b) in healthy volunteers and oncology as the main therapeutic areas.

Kara started her career as a Clinical Operations Associate with a small local CRO and worked her way up the CRA pathway. She moved from the CRO sector to work for two global pharmaceutical companies in their Clinical Research Departments (Australian affiliates). In 2013, Kara returned to the CRO sector joining INC Research's Early Phase Development group as a Senior Project Manager and was quickly promoted to Project Director. In the last 5 years Kara has held to Director level leadership positions in Project Delivery, most recently she led a department of 60 project management professionals delivering over 160 clinical trials.

Kara has a passion for developing high performing teams who provide high quality project delivery services for biotech customers.

Kara joined Biointelect in August 2024, to work with Jacqui Wade, building full service clinical trial capabilities.

Dr Alysha Elliott

Project Manager, Clinical Affairs and Director Services

Dr. Alysha Elliott has over 15 years of experience in the Life Sciences industry. She holds a Ph.D. in Molecular Bioscience from the University of Queensland, focusing on drug discovery. Her expertise spans molecular biology, microbiology, biochemistry and antimicrobial drug development.

Throughout her career, Alysha managed preclinical evaluations of novel antimicrobials, led a crowd-sourcing screening program with over 330 participant groups, and conducted contract research for Biotech companies. She received the prestigious Endeavour Executive Fellowship in 2018, gaining commercialisation experience at Cambridge Enterprise (UK) and the biotech start-up Inflazome Pty Ltd, later acquired by Roche in 2020. Alysha's work has resulted in over 70 peer-reviewed research articles and numerous awards, including the Antibiotic Guardian award for Research UK, finalist recognition in The Australian Innovation Challenge, Australian Museum Eureka Prizes, and the AusBiotech-GlaxoSmithKline Student Excellence Award in Translational Research. Her interdisciplinary infectious disease research attracted funding from globally recognised bodies such as the Wellcome Trust (UK), the National Institutes of Health (NIH, USA), and CARB-X (Combating Antimicrobial Resistant Bacteria Biopharmaceutical Accelerator), supported by BARDA, GAMRIF, Wellcome, the Bill and Melinda Gates Foundation, among others.

Alysha joined Biointelect in 2023 as a Project Manager, providing expertise in infectious diseases and facilitating the development of innovative therapies, and technologies with a passion for clinical study management.

Brian Gilmartin

Director, Regulatory Affairs

Brian Gilmartin has more than 20 years of international experience in the pharmaceutical industry, having worked across Europe, Asia Pacific, Japan and ANZ. He holds a Master of Science in Bioinformatics and a Bachelor of Science (Honours) in Biological Sciences with a Biotechnology specialty.

Earlier in his career, Brian began as a Bioinformatics computer associate working in drug discovery startups before joining a genome project at the University of Cambridge, Institute of Medical Research. Brian crossed over to the pharmaceutical industry in 2004, focusing on regulatory affairs and gaining substantial experience in new product development, manufacturing and clinical with leading commercialisation consulting companies.

During the past decade, Brian has channeled his broad exposure across the pharmaceutical industry into building out a pharmaceutical products and services company across the JAPAC region supporting clinical trial supply, early access programs, unlicensed supply and the commercialisation of lifesaving medicines to address the unmet medical needs of patients.

Brian joined Biointelect and Biocelect in November 2023.

Dr Danijela Mirosa

Director, Commercialisation Strategy

Dr. Danijela Mirosa brings 20 years of experience across the biotech, biopharmaceutical, and healthcare innovation sectors. Holding a PhD in Biomedicine from the University of Melbourne and an MBA from Melbourne Business School, Dani has a deep understanding of the drug development process gained during her time as a Senior Scientist in Biotechnology R&D at Amrad and CSL Limited. Her expertise spans the product lifecycle from scientific research to strategic and commercial leadership.

In her early career, Dani spent 12 years leading successful product launches and commercialisation strategies in large multinational biopharma companies across various therapeutic areas and funding environments, including numerous first-in-therapy area launches across diverse therapeutic areas, including Oncology, Haematology, Immunology, and Rare Diseases. This included Country Leadership Team roles in Strategy & Operations, Patient Services, and as the Franchise Director for Oncology at Takeda for the Oceania Cluster. More recently, Dani has worked with start-ups and emerging companies in the fields of digital health tech, patient engagement, and AI-powered precision medicine, supporting business case development, refining marketing and commercialisation strategy, and exploring new market and geographic entry opportunities.

Dani has joined Biointelect in 2024, with her diverse skill set and experience across the full spectrum of the life sciences industry, she is well-positioned to provide strategic guidance and support to Biointelect's clients as the Director of Commercialisation Strategy.