NOVOTECH
The Asia Pacific CRO

Accelerating drug development leveraging Australia leading destination

Dr. Yooni Kim,
Vice President, Global Head of Clinical Services at Novotech

44th KABC - AKBC Joint Meeting
September 7- 8, 2023

Biotech-Specialized Full-Services CRO

- **Headquartered in Sydney Australia since 1995 & Established Korean office in 2000.**
- **The biggest CRO in Australia & Top-ranked CRO in terms of number of trials approved by MFDS in Korea**

Feasibility

Detailed feasibility to identify the optimal countries, sites and investigators for the study

Expert consulting services

CMC/manufacturing, toxicology, clinical/medical and regulatory affairs and specializes in preparing products to swiftly enter the clinic or gain marketing approval.

Clinical services

Project management, patient recruitment, monitoring and SDV

Robust IT systems

Accredited to ISO 27001 (Information Security Management System)

Related Trial Services

- 1 Central Lab
- 4 Bioanalytical Labs
- SMO capability across South Korea and China
- 2 Dedicated Phase I Units

Biometrics

Including data management, biostatistics, PK analysis and modelling

Regulatory

Ethics and regulatory submissions, drug importation and governance

Independent QA services

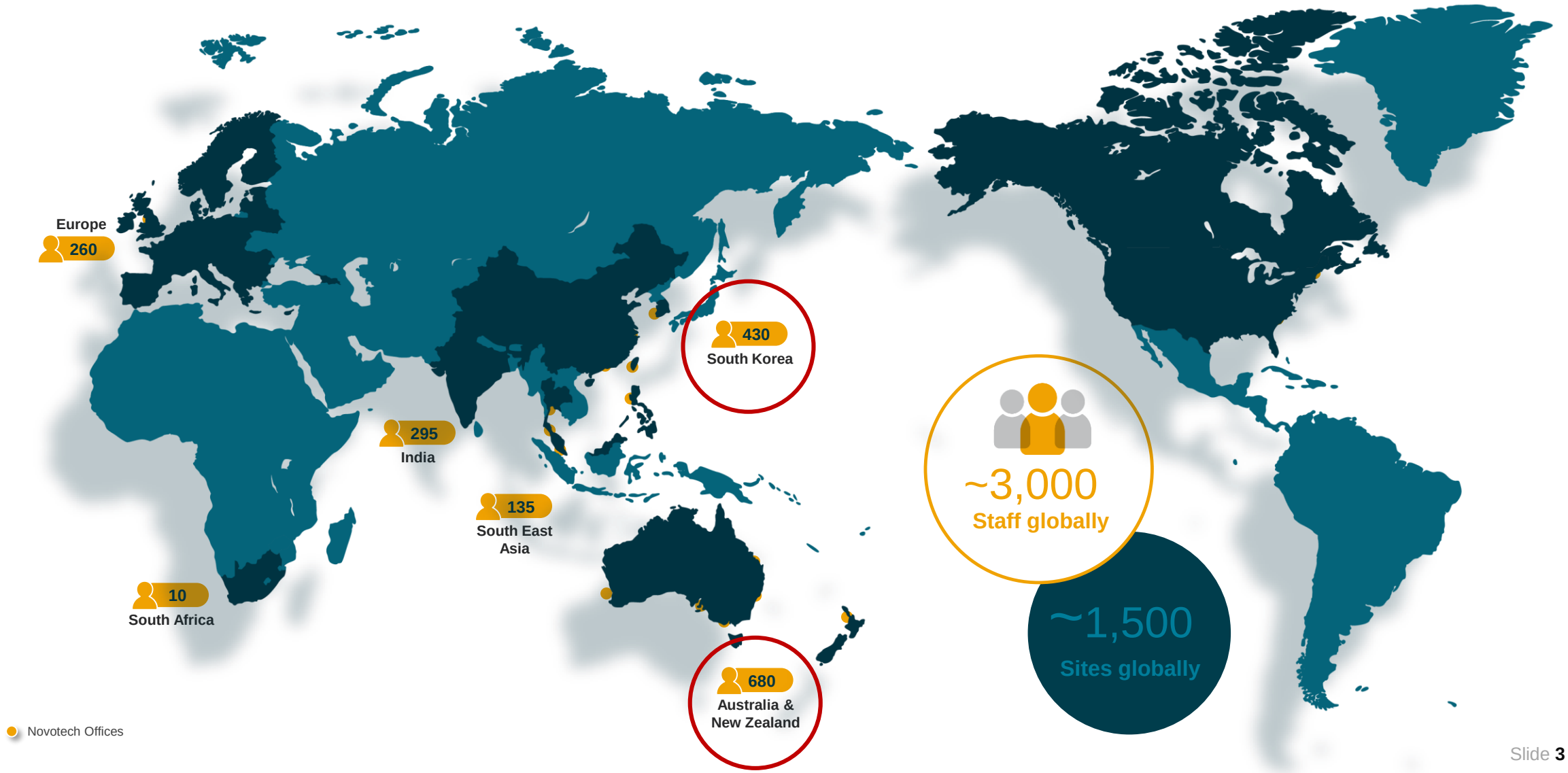
Accredited to ISO 9001

Medical services and safety

Includes medical monitoring, protocol and clinical study report writing

Local relationships, Global execution

Partnering with sites, PIs and regulatory authorities to provide best in-country solutions



*Includes contractors

Novotech Drug Development Consulting

Expertise in global drug development and FDA regulatory expertise

Inception

Regulatory & Clinical Strategy

Partnering with biotechs to define the optimal drug development strategy and value creation

Development

Intelligent Drug Development

CMC/manufacturing, toxicology, clinical/medical and regulatory affairs experts with extensive industry experience covering all phases of drug development.

Approval

Regulatory Success

Novotech offers a fully integrated regulatory affairs team with an experienced, speed orientated mindset to increase the probability of regulatory and commercial success.

Novotech’s comprehensive services for Biotechs

Ability to adapt to Biotech needs to build and accelerate global clinical development strategies

Development Partner

- Development partner approach
- Experienced drug developers and regulatory strategists
- Global agency experience and expertise
- Medically and scientifically driven
- Robust feasibility and site intelligence for accelerated operational execution

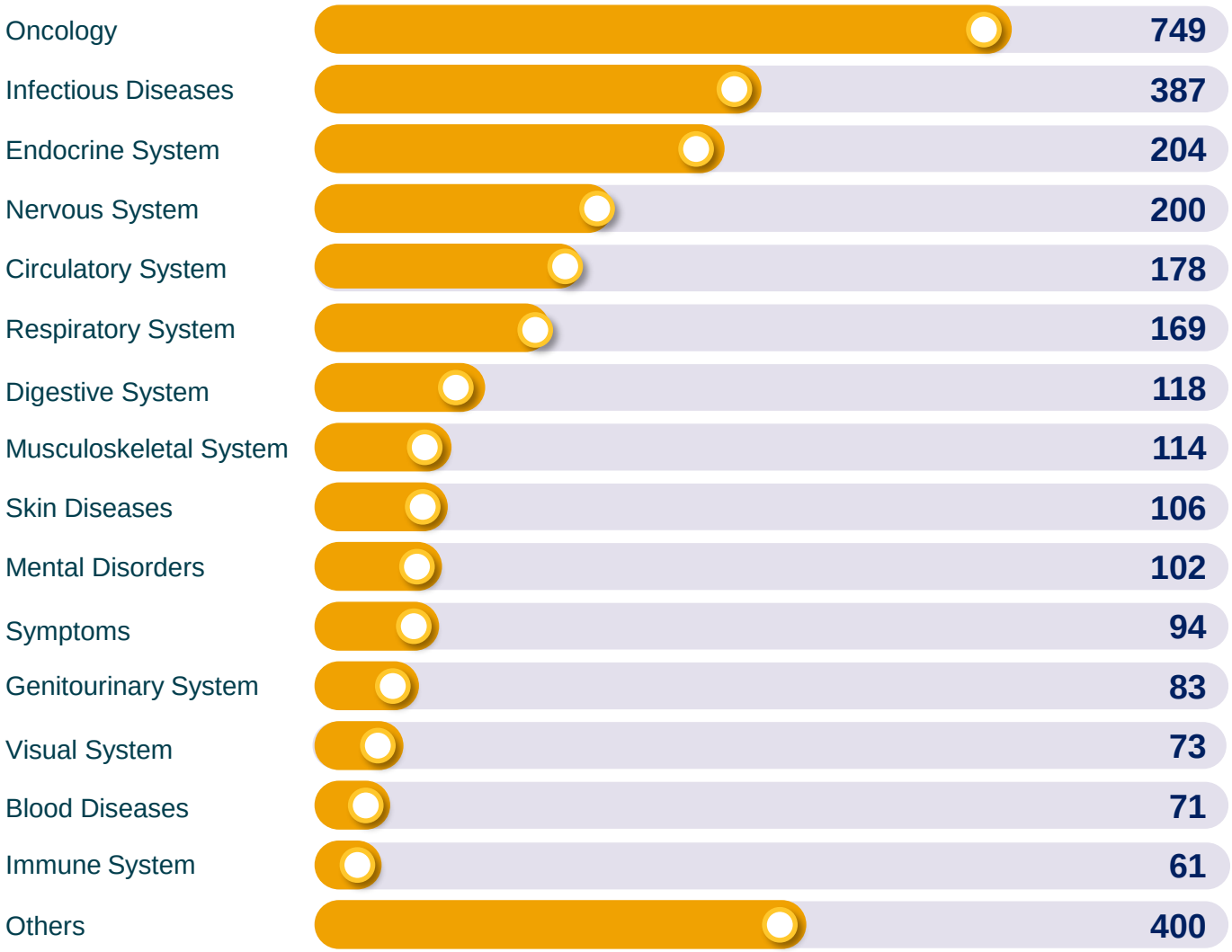
Sophisticated Operational Infrastructure

- Robust, global project management, ISO accredited processes
- Local clinical teams – supported by global infrastructure
- Global biometrics, medical monitoring and pharmacovigilance
- Internal quality assurance
- Bioanalytical and central laboratory

Cutting-Edge Technology

- Veeva single suite of clinical systems
- Accredited EDC builders in Medidata, Viedoc and Veeva
- Decentralized clinical trials infrastructure and technology
- Partnerships that provide:
  - Access to prescribing data and EMRs for patient identification
  - Access to NGS screening data for precision medicine studies

Novotech has extensive therapeutic experience with >3,000 trials across a broad range of therapeutic areas



 # trials (as of January 2023), ***Other*** *– Regulatory, Audit, Feasibility, Development Anomalies, Health Status Factor, Sexual Health, Morbidity/Mortality, Sleep-Wake Disorders & Injury and excluding BE Studies*

Novotech's clinical development partnerships have resulted in over 100 registered products by the FDA, NMPA, EMA, and MFDS

Oncology

- **Abraxane Paclitaxel (**Cancer**)**
- **Folotyn (**Lymphoma)
- **Fotivda (**Renal cell carcinoma)
- **Istodax (**T-cell lymphomas)
- **Levact (**Chronic lymphocytic leukaemia)
- **Metvix PDT** (Skin cancer)
- **Nerlynx** (HER2-positive breast cancer)
- **Rubraca** (Ovarian cancer)
- **Tarceva (**Lung and pancreatic cancer)
- **Talzenna** (Metastatic Breast Cancer)
- **Unituxin** (Neuroblastoma)
- **Xpovio** (Multiple Myeloma)
- **Xtandi (**Prostate cancer)
- **Zytiga** (Prostate cancer)
- **Neupogen** (filgrastim)- Cancer
- **Herceptin** (trastuzumab)- breast, stomach, and esophageal cancer
- **Oncorine (H101)-** Head and neck cancer

Infectious Diseases/Metabolic Disorders/Neurology

Infectious Diseases

- **Daklinza** (Hepatitis C)
- **Harvoni** (Hepatitis C)
- **Kodatef** (Malaria prevention)
- **Solvaldi** (Hepatitis C)
- **Trogarzo** (HIV)
- GC Flu H5N1 Multi Injection (Vaccine)
- Zyvox (linezolid)- Drug resistant bacterial infections

Metabolic disorders

- **Kengreal** (Coronary intervention)
- **Ocaliva** (Obeticholic Acid) (Primary biliary cirrhosis)
- **Praluent** (High Cholesterol)
- **Zurampic** (Gout)

Neurology

- **Aridasta** (Schizophrenia)
- **Vimpat** (Partial-onset seizures)
- **Xadago** (Parkinson's disease)
- **Cymbalta** (duloxetine)- Depression and Anxiety disorders
- **Zyprexa** (olanzapine)- schizophrenia and bipolar disorder
- **Strattera** (atomoxetine HCL)- ADHD

Dermatology/Respiratory/ Musculoskeletal/Eye disorders

Dermatology

- **Cosentryx** (Psoriasis)
- **Dupixent** (Atopic dermatitis)
- **Solaraze** (Actinic and solar keratosis)
- **Taltz** (Psoriasis)
- **Dalvance** - Skin Infectious diseases
- **Baxdela®** (delafloxacin)- Skin Infectious diseases
- **Finacea** (azelaic acid gel 15%)- Rosacea and Acne

Respiratory

- **Bevespi Aerosphere** (COPD)
- **Xolair** (omalizumab- e25)- Asthma
- **Esbriet** (perfinedone)- idiopathic pulmonary fibrosis

Musculoskeletal

- **Zilretta** (Osteoarthritic knee pain)

Eye disorders

- **Lucentis** (Wet AMD)
- **Arxxant** (ruboxistaurin) - Diabetic retinopathy

Blood Diseases/Genetic disorders/Others

Blood disorders

- **Empaveli** (Paroxysmal Nocturnal Hemoglobinuria)
- **Northera** (Orthostatic hypertension)
- **ReFacto** (antihemolytic factor/ recombinant)- Hemophilia A
- **Kogenate FS** (Recombinant Factor VIII)- Hemophilia A

Genetic disorders & others

- **Depodur** (Post-operative pain)
- **Firazyr** (Hereditary angioedema)
- **Galafold** (Fabry disease)
- **Orladeyo** (Hereditary Angioedema)
- **Xiaflex** (Dupuytren's and peyronie's contracture)
- **PremPro** (conjugatedestrogen/ medroxyprogesterone)- Menopausal hormone therapy
- **Premarin** (conjugated estrogen)- Menopausal hormone therapy
- **AJOVY** (fremanezumab)- migraine
- **OxyContin** (oxycodone)- Chronic pain
- **Palladone** (hydromorphone)- Chronic pain

Scientific, regulatory, medical and operational expertise in advanced and novel therapies

Pre-clinical ➡ clinical ➡ marketing authorization

Immuno-oncology

134 Trials

- Checkpoint Inhibitors
- Monoclonal Antibodies
- Bi/trispecific Antibodies
- Antibody Drug Conjugates
- Cell Therapies
- Cancer Vaccines
- Oncolytic Virus

Vaccines

98 Trials

- mRNA
- Plasmid DNA
- Conjugate Vaccines
- Subunit Vaccines
- Recombinant Vector
- Live Attenuated Vaccines

Cell & Gene

43 Trials

- CAR-T
- Allogeneic, Autologous
- T Cell Receptor (TCR)
- Stem Cell Therapy
- NK Cell Therapy

- In vivo gene therapies
- Ex vivo gene therapies
- Oncolytic viruses

RNA

41 Trials

- mRNA
- Antisense RNAi

Microbiome

11 Trials

- Gram Positive Bacteria
- Gram Negative Bacteria
- GMO Bacteria

Total number of trials as at end of Jan 2023

Novotech and our employees have won numerous awards and recognitions in the CRO industry

2020

- Frost & Sullivan 2020 Best Practices Award – Asia-Pacific CRO Company of the Year
- AUSTCHAM KOREA AKBA 2020 – Australia-Korea Business Awards
- WGEA Employer of Choice for Gender Equality
- CRO Leadership Awards 2020 – Quality
- Great Place To Work. Certified
- Certified System – Information Security ISO 27001 – SAI Global

2021

- Frost & Sullivan 2021 Best Practices Award – Asia-Pacific CRO Company of the Year
- CRO Leadership Awards 2021 – Compatibility
- Great Place To Work. Certified May 2021 – May 2022 AUS
- Great Place To Work. Certified May 2021–May 2022 India
- Top 10 Global CRO – Novotech – The Asia Pacific CRO – WCG CenterWatch

2022

- Frost & Sullivan 2022 Best Practices Award – Malaysia Biosimilars Company of the Year Award
- Asia Pacific Cell & Gene Therapy Excellence Awards 2022
- Top 10 Global CRO – Novotech – The Asia Pacific CRO – WCG CenterWatch
- Best Workplaces – Great Place To Work. Korea 2022
- Best Workplaces for Millennials – Great Place To Work. Korea 2022
- Best Workplaces for Women – Great Place To Work. Korea 2022

2023

- Champion CRO Leadership Awards 2023 – Compatibility

*Top 10 Global CRO based on 2021 WRG CenterWatch Site Survey as voted by 3700 HCPs globally

Attractiveness of Australia as a Trial Destination for Early Phase

Quality

Clinical Data in Australia is **accepted by FDA and EMA**.

Speed

Start-up timelines of around **6 to 8 weeks** for private sites, from Ethics Committee submission to approval.

Efficiency

No CTA or IND required just ethics approval and notification to the TGA. FIH data is obtained earlier in development, therefore earlier ‘next round’ funding supported and more meaningful IND/CTA applications submitted.

Cost

Favorable R&D refund scheme with up to **43.5%** R&D cash refund.

Biotech companies can initiate a clinical trial in Australia in parallel to the preparation of a US IND submission, often commencing dosing within a single review cycle of six-to-eight weeks from submission.

Case study:
Leveraging Australia's speed - Phase 2 metastatic refractory solid tumor study

2 sites in Australia

South Korea-based sponsor looking to take advantage of Australia’s regulatory and rapid clinical trial environment Novotech secured prompt HREC approval & managed site initiations. Novotech’s strong PI and site relations allowed Sponsor A to accelerate feasibility activities, further expediting trial timelines

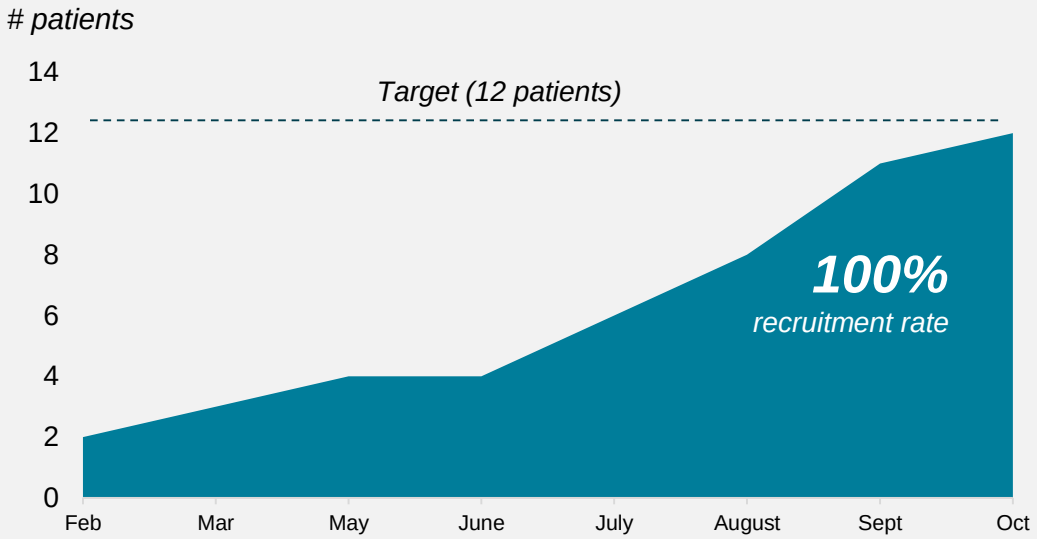
15 months from study start to last patient enrolled

- Novotech secured prompt HREC approval and managed site initiations.
- Novotech recruited 1 cohort within just 4 weeks of site initiation, with overall recruitment closing 2 weeks early.

Head of Clinical Development, Sponsor A

“Novotech not only efficiently guided us through the Australian regulatory process to deliver the trial quickly, their in-depth knowledge of South Korea’s regulatory environment meant we could use the resulting trial data for both regulatory processes. This was of great benefit to our business and development timelines.”

Cumulative patient recruitment over time



Case study 2

Early engagement leading to streamlined clinical trial delivery

- Sponsor B is a South Korean biotech specializing in the development of innovative new drugs for infectious disease indications
- Sponsor B contracted the Novotech Drug Development Consulting (DDC) team for gap analysis
- This resulted in Novotech being full medical writing (protocol synopsis and IB) for Phase II trial in Australia followed by the Phase I patient trial in NZ.

Onychomycosis program:

Phase I — *Enrolment* ✓

Phase II — *July start for MW*

Partner and site rationale:

- **Why Novotech?**
  - Preclinical Consulting to Clinical Capabilities In-House.
- **Why Australia?**
  - Maximize R&D rebate

Case study 3

Assisting a biotech client with planned US IND submission following Phase I

- Sponsor C is a South Korean biotech specializing in the development of novel therapies for metabolic diseases NASH
- Sponsor C contracted the Novotech Drug Development Consulting (DDC) team for gap analysis and thereafter engaged our medical writing team for protocol synopsis and IB writing
- Sponsor C contracted Novotech for single site Phase I health volunteer and patient study in Australia
- Sponsor C is planning to leverage Phase I data for US FDA's IND approval.

NASH program:

Phase I — *Enrolled >70/ ~100*

Partner and site rationale:

- **Why Novotech?**
  - Consulting capabilities and strong local experience and footprint
- **Why Australia?**
  - Maximize R&D rebate

Case study:
From Australia Phase I to a Global Phase III

Background

The sponsor is a publicly listed biotech company based on the US West Coast, specializing in the development of Oncology drugs.

Relationship initiated in 2018

In July 2018, the client contracted Novotech for a Phase I rescue study with two sites in Australia.

The study was rescued from a global CRO. The client decided to move away from the CRO due to unsatisfactory service.

The foundation for larger projects across Asia-Pacific

In 2019, the client contracted Novotech for a Phase I/II (in January) and Phase II (in December) with sites in Australia, New Zealand, Malaysia, South Korea, Taiwan, Thailand, Singapore and Hong Kong.

In July 2020, the client awarded Novotech the global lead on the Phase III NSCLC including Global Project Management, Clinical, Regulatory and Medical activities in APAC and Vendor Management (all vendors contracted directly).

The Phase III will involve over 90 sites across Asia-Pacific over 70 months.

"Thank you for […] your leadership through this process. The efficiencies we are leveraging from Novotech and [sponsor]'s long-standing collaboration are apparent when we consider that less than 6 weeks ago, we were holding the first [kick-off meeting] […]

Many thanks to the entire team for aligning towards our goal to have patients on [treatment] by year end and identifying opportunities ***where we can streamline our processes and leverage our document/process standards to move us quickly towards this important goal…in the middle of a global pandemic […] !!"***

Director Clinical Operations at Sponsor

NOVOTECH™
The Asia Pacific CRO

Thank You

www.novotech-cro.com