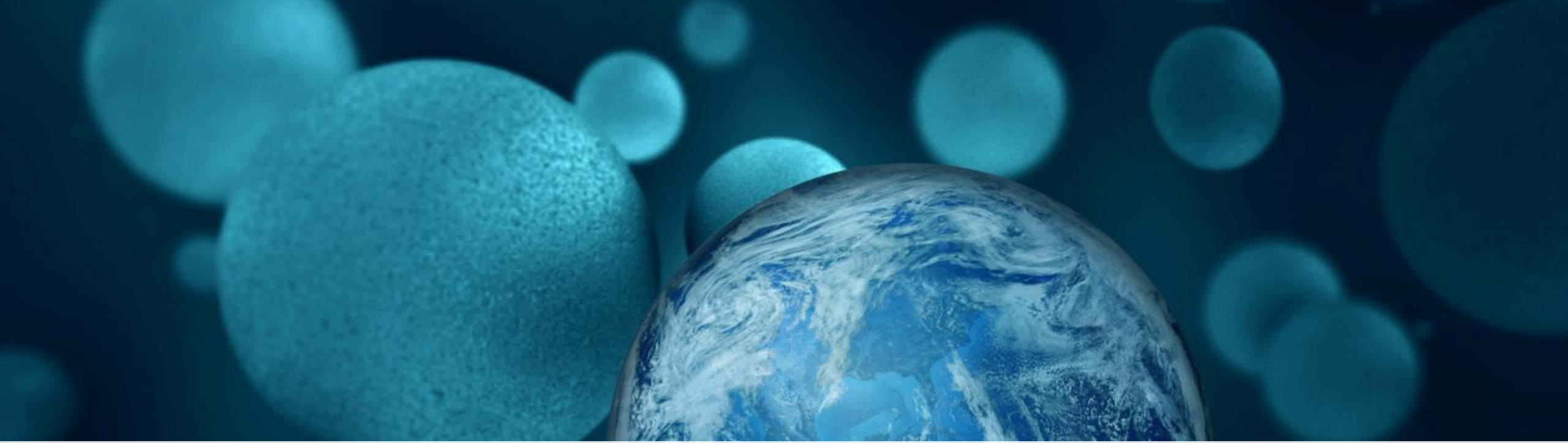

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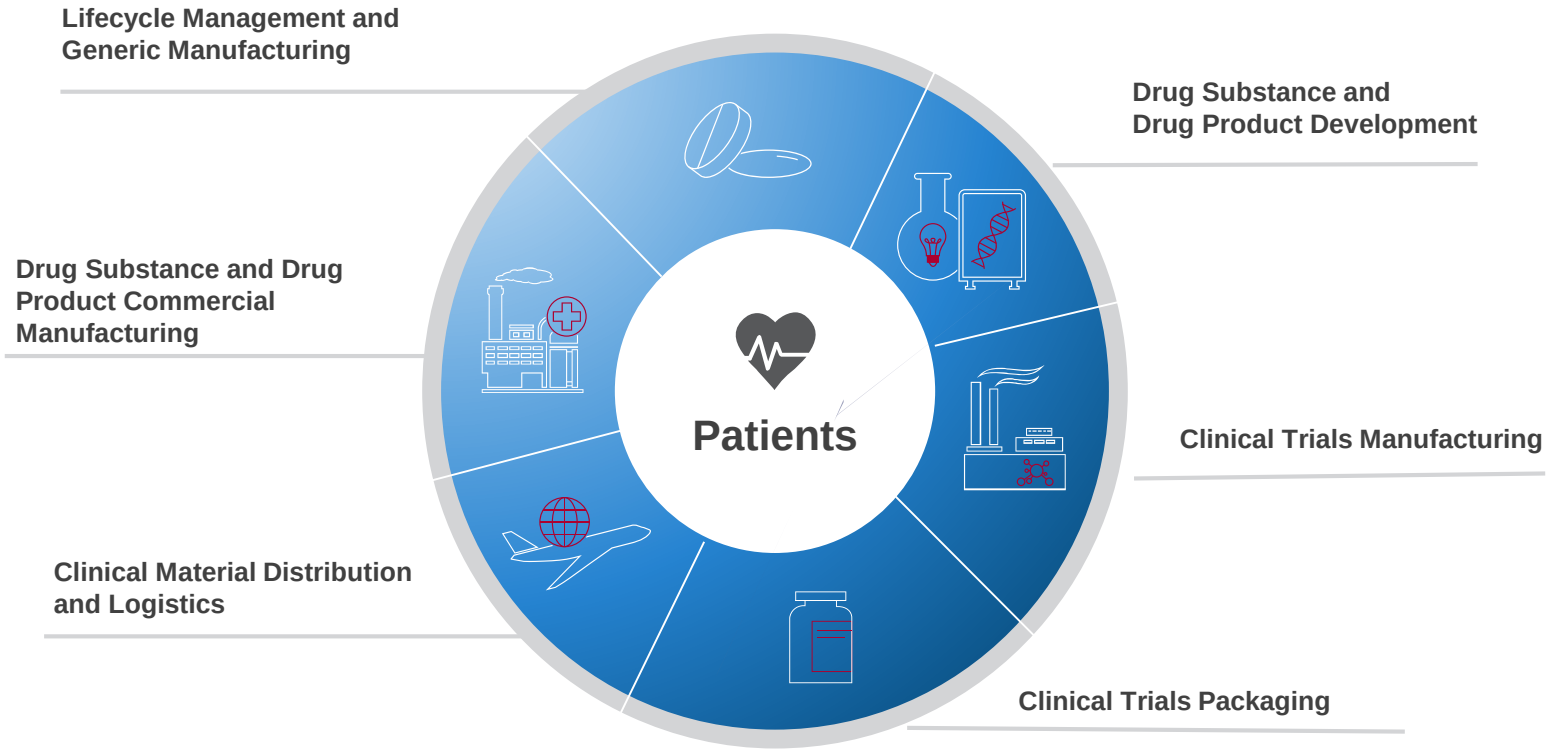
Capitalizing on the Australia and South Korea corridor to develop biopharmaceuticals

Dr Ryan Parlett
Director Business Management
40th AKBC-KABC Joint Meeting

Pharma Services is the leader in Drug Development, Trial Logistics and Manufacturing

Patheon — ThermoFisher SCIENTIFIC — Fisher Clinical Services



20 billion & **156 million**

solid doses **sterile doses**

representing 75% of all dosage forms

1000+ molecules developed	**4,000+** clinical trials supported
50+ large molecule drug substance	**200+** small molecule drug substance
800+ clients	**12,000** employees

Flexible business models

Customized to meet your unique needs

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Where we are

Development, clinical supply and commercial manufacturing

An integrated global network

ThermoFisher SCIENTIFIC

Brisbane, Australia (BNE)

>5 years experience and expertise in cGMP manufacturing of biologics products in an award winning brand new facility

- Phase I, II and phase III clinical production and supply to Asia, US, Canada, EU, and Australia

Fed-batch, perfusion and XD® technology

- 100% single-use bioreactors, HyClone, GE XDR and Sartorius
- 250 L – 2000 L scale
- 50 L – 500 L Perfusion / XD® processes

Separate, dedicated DSP suites

In-house QC and QA

Strong track record of performance:*

- ≥95% RFT
- ≥95% ROTD
- 3 regulatory inspections and numerous client audits: 0 critical observations

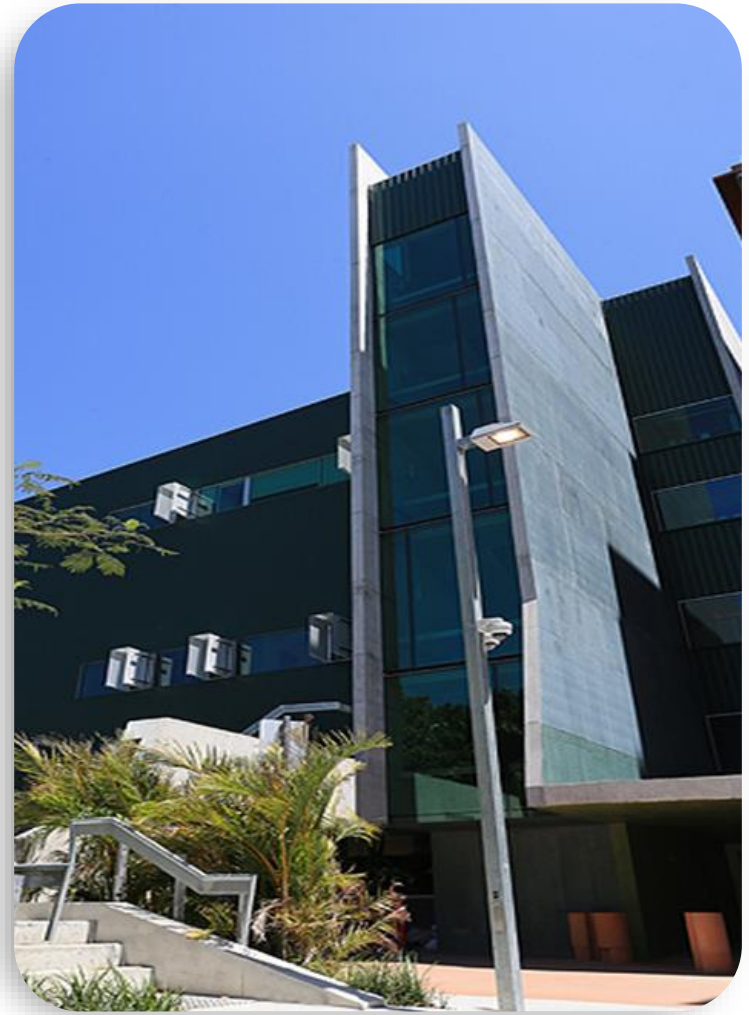
Global project management – experienced tech transfer teams

- Leadership team all have global industry experience

Australian R&D Tax Incentive of up to 43.5% of investment

* Statistics apply to 2017-2018

Clinical & commercial manufacturing



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Australian R&D Tax Incentive

Benefit is dependent on aggregated turnover:

Turnover/income	R&D tax offset rate available
Aggregate world-wide turnover less than AU$20 million	43.5% refundable
Aggregate world-wide turnover of AU$20 million or more	38.5% non-refundable

For companies eligible for the 43.5% refundable tax offset, this translates to a **cash refund** of $435,000 for every $1 million spent on R&D activities for companies that have sufficient tax losses – Non-dilutive capital

Overseas Finding - Mechanism to claim expenditure on activities conducted outside of Australia. Key requirements:

- The overseas activity needs to be an eligible R&D activity
- Have a significant scientific link to an Australian core activity
- Cannot otherwise be conducted in Australia due to a technical rationale
- Costs of the overseas activities needs to be less than the costs of the Australian activities over the life of the project

Need to consider cross-border and corporation and international tax issues – seek professional advice

Shaping the demand: Large and small pharma

Direction of pharma and biotech

- Forge strong partnerships that keep patients at the core
- Relentless focus on accelerated time to market
- Reducing operating costs and improving productivity
- Assuring quality and collaborating with regulators

Large pharma trends

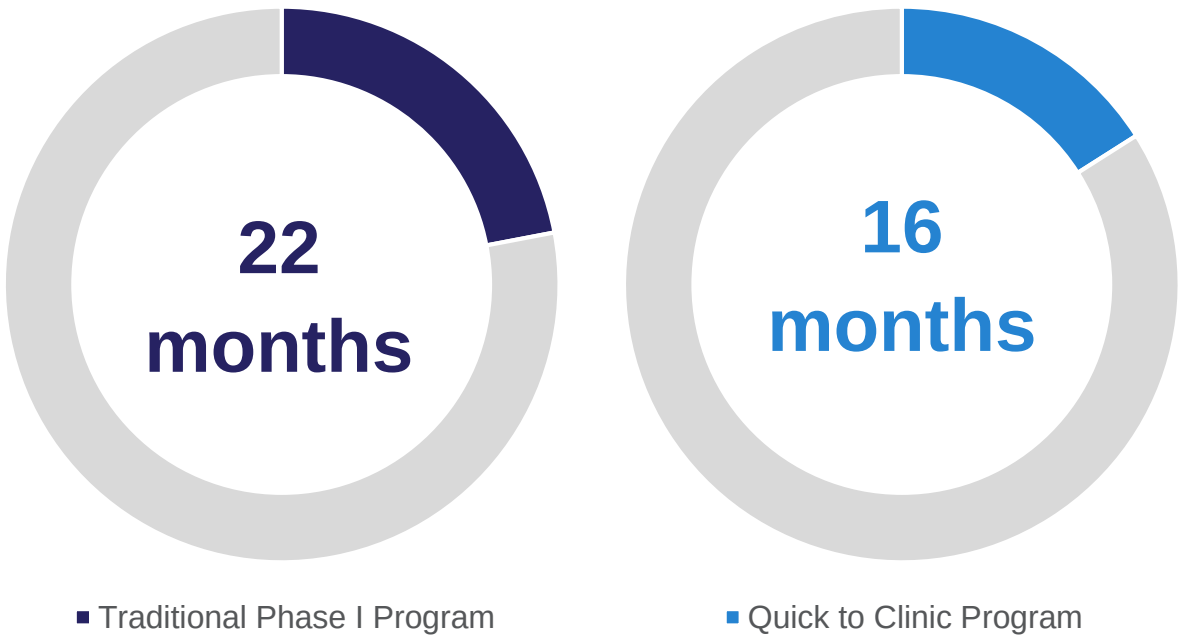
- Optimize networks and drive productivity
- Flexibly manage capacity needs
- Reduce capex requirements while accessing world-class expertise

Emerging biopharma trends

- 80% of new compounds held by small/emerging pharma and biotech
- Leverage CDMO manufacturing infrastructure and expertise
- Limited internal capabilities

Australian value proposition – Cost savings, quick timeline and quality data

Patheon® Quick to Clinic™ for biologics manufacturing



- Fast, Flexible, Full development for First-in-Human studies

Australia – Key clinical trial differentiators

- **Speed**

  Very fast clinical start up times
  - HREC submission to dosing for studies is ~6 weeks
  - Fast track phase 1 First-in-Human studies

- **Favourable regulatory environment**

  No CTA or IND required just ethics approval and notification to the TGA

- **Quality**

  Data generated from studies is recognised by major regulators and big pharma

Underpinned by Australian R&D Tax Incentive

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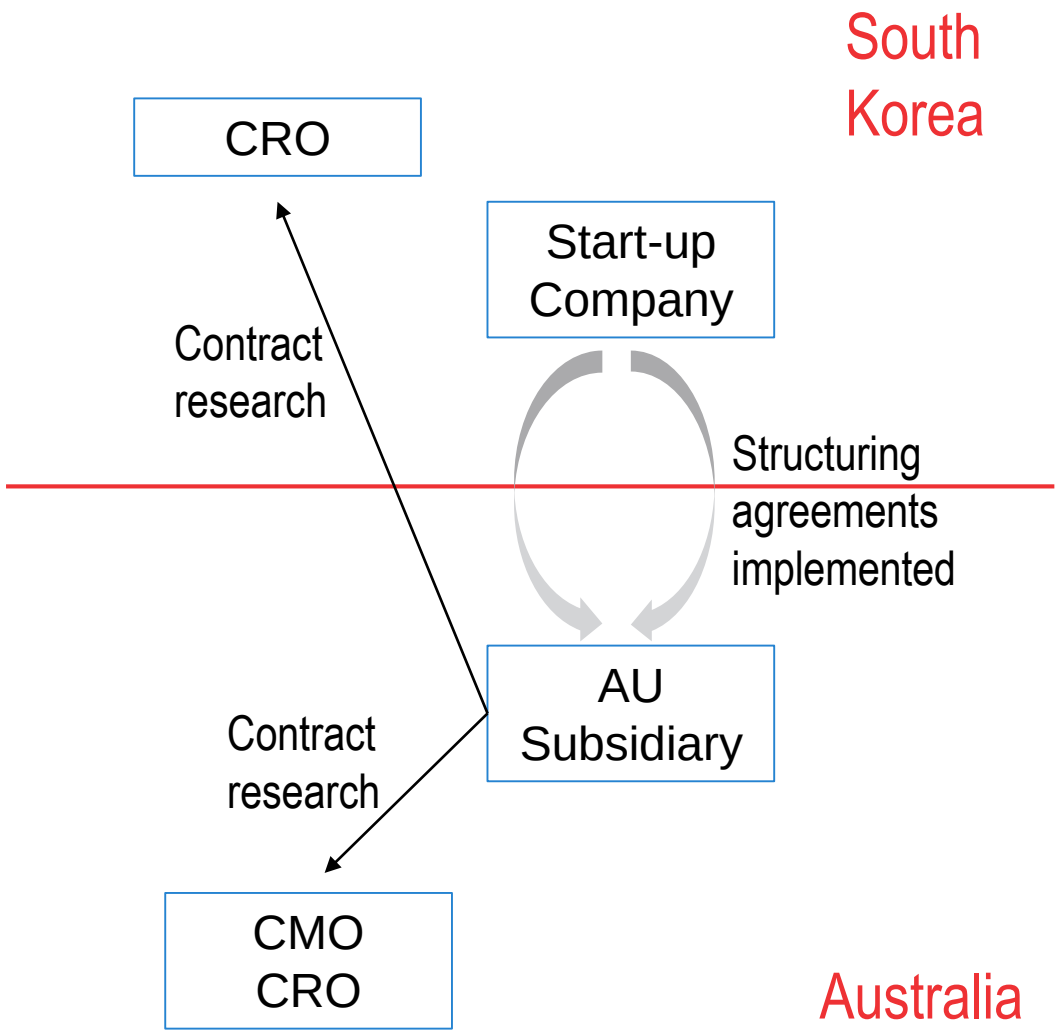
Case study

- South Korean based Start-up
  - Venture capital funded
  - All shareholders own less than 40% equity
  - No ordinary income.

- Australian subsidiary
  - Implemented structuring agreements
    - Basic example can include:
      - All IP is owned by Parent Start-up Company
      - AU Subsidiary has economic ownership in outcome of R&D
  - AU Subsidiary financed through debt and/or equity by Parent
  - Transfer pricing and corporate international tax considerations addressed.
  - R&D activities undertaken by the AU Sub



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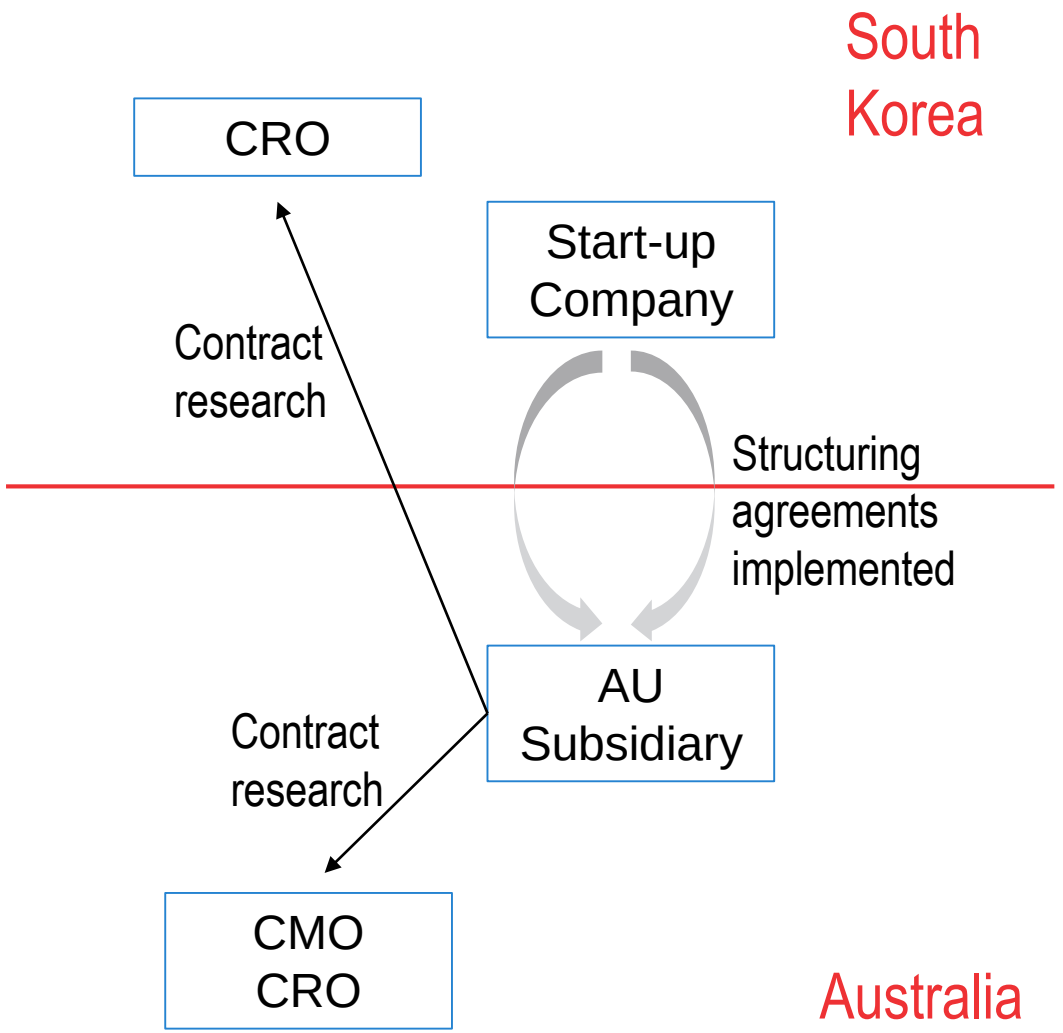
Case study

- **Activities undertaken in South Korea**
  - Cell line generation
  - Small scale manufacturing process development
  - Animal toxicology studies
  - Clinical trials
    - Phase 2
  - Total R&D costs in South Korea - $6,300,000
- **Activities undertaken in Australia**
  - Engineering batch to supply material for tox studies
  - GMP manufacturing to supply phase 1 and phase 2
  - Clinical trials
    - Phase 1
    - Phase 2
  - Total R&D costs in Australia - $8,465,000



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Case study

- In 2019, AU Sub has R&D expenditure of $14,765,000
- Did not receive any ordinary income during income year
- AU Sub's aggregate turnover is less than $20 million
- AU Sub is eligible for the 43.5% refundable R&D Tax Incentive
- Applied for an Overseas Finding and successfully approved
- **Full cash benefit of 43.5 cents in dollar received**.

Potential Outcome	With R&D Incentive
Assessable income	0
Deductions	(14,765,000)
Addback R&D expenditure subject to incentive (notional Expenditure)	14,765,000
Taxable income	0
Tax payable (@ 28.5% company tax rate before offset)	0
R&D refundable tax incentive (@43.5%) – received as cash refund	(6,422,775)
Cost of program after R&D Tax Incentive claim	8,342,225

Outcome:

- Fast tracked timeline
- Reduced development costs
- Quality manufacturing and clinical data

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Thank you

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