What CMOs Need to Know About Running Clinical Trials in New Zealand

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Overview

- **Rapid Start-up:** 4-6 weeks regulatory and ethics approval, standardised agreements, no IND, IMPD or QP required
- **Quality:** Data accepted by all major RAs including FDA/EMA
- **Supportive regulatory environment:** welcomes innovative/adaptive trial designs as well as gene editing trials
- **Disease Profile**: Similar to USA and Europe, high prevalence of major conditions
- **Participants:** Access to wider population, high trust in clinical research, treatment-naïve patients, broad ethnic diversity
- **Reverse Seasonality:** Extending seasonal clinical trials
- **Efficiency:** 15-43% Research and Development Tax Incentives, highly favorable currency exchange

What do we look for in clinical development?

- Ongoing pressure to:
  - Accelerate timelines
  - Manage regulatory and EC complexity
  - Recruit participants quickly
  - Early decision making
  - Maintain study execution and data quality

- Speed
- Scale
- Cost
- Quality
- Impact on Portfolio

Why Does this Matter to CMOs?

Cycle time = enterprise value

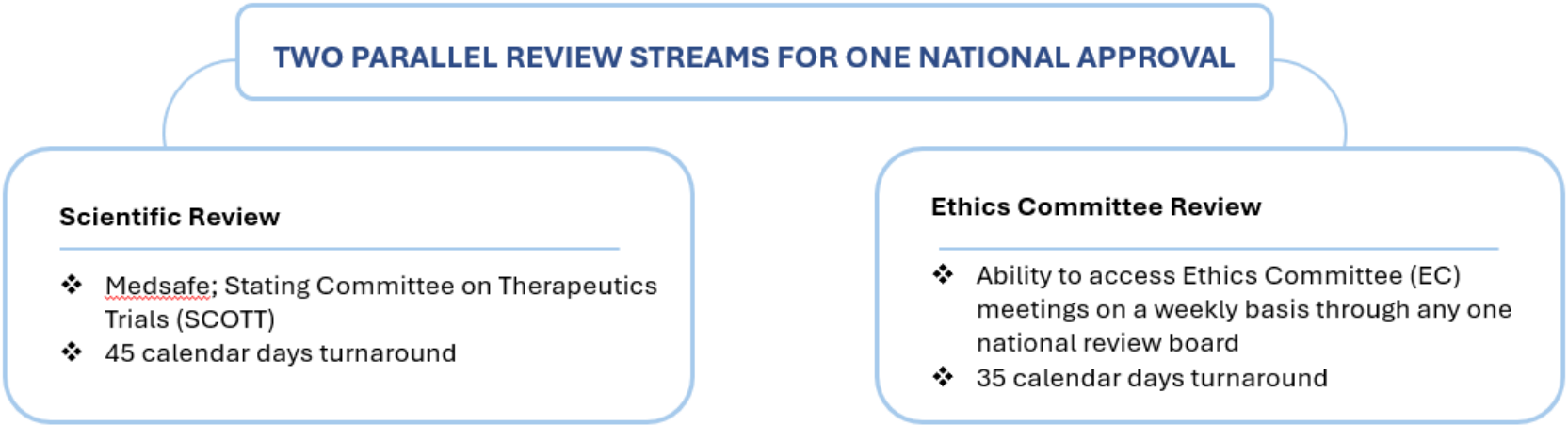
Early data quality drives go/no-go decisions

Geography choice impacts cost, timelines, and risk

Strategic Value Proposition

- Speed: materially faster early-phase execution
- Quality: highly reliable, regulator-trusted data
- Cost: meaningfully lower than US/EU
- Tradeoff: limited scalability

Regulatory and Ethics Timelines



- No IND, IMPD, CTA or QP required for clinical trials in NZ
- Rapid Start-Up: 4-6 weeks for regulatory and EC approval

Pro #1: Speed as a Competitive Advantage

~30-DAY APPROVALS COMMON

PARALLEL REGULATORY + ETHICS REVIEW

RAPID SITE ACTIVATION

CAN ACCELERATE FIH → POC TIMELINES BY MONTHS

Pro #2: High-Confidence Data

- Experienced investigators, strong GCP adherence
- Lower variability vs fragmented US sites
- High protocol compliance
- Data accepted by FDA/EMA

Pro #3: Cost Efficiency

- Lower per-patient costs vs US/EU
- Reduced monitoring burden
- Lean infrastructure
- Favorable currency exchange (USD/EUR vs NZD)

Pro #4: Early-Phase Experience

- Globally recognized Phase I capability
- Strong healthy volunteer recruitment
- Efficient dose escalation workflows
-  Ideal for FIH, SAD/MAD, and POC studies

Pro #5: Recruitment Dynamics

- Less competition vs major markets
- Access to treatment-naïve patients
- Strong retention and compliance
- Useful for clean signal detection

Con #1: Structural Scale Limitations

Population ~5M

Not viable as sole geography for Phase III

Limited rare disease pools

Requires early planning for global expansion

Con #2: Geographic Reality

- Distance from US/EU sponsors
- Logistics: IP, biosamples, central labs
- Time zone friction for oversight
- Requires strong CRO/site partnerships

Con #3: Capacity Constraints

Finite number of sites

Investigator bandwidth can be limiting

Competition for top Phase I units

Where NZ Wins in a Portfolio

First-in-human and early signal detection

Speed-critical programs

Mechanism validation before scaling

De-risking assets before large capital deployment

Where NZ May Not be the Answer

- Large global Phase III
- Programs needing rapid scale-up
- Highly logistics-intensive protocols
- Ultra-rare indications with tiny pools

Takeaways

1. Use NZ as an early-phase accelerator
2. Combine with US/EU/ROW for scale
3. Leverage for faster decision-making
4. Think of NZ as a strategic tool—not a standalone solution