speed to **study**™

"Speed to study offers a value-added service for the acceleration of drug candidate to proof of concept."

Andrew Castles
General Manager, Melbourne

NORTH AMERICA · EUROPE · ASIA PACIFIC

pci PHARMA SERVICES

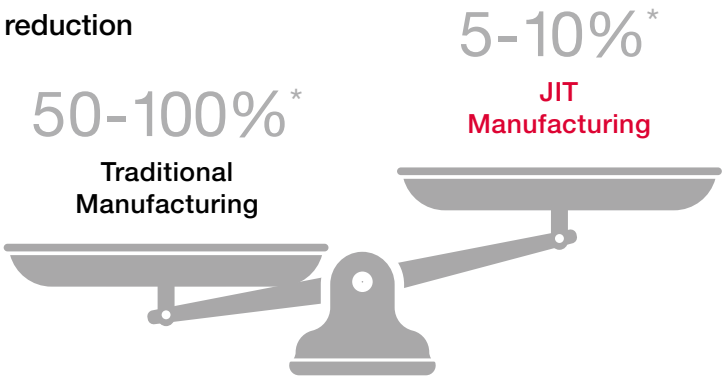
How does Speed to Study™ work?

Speed to Study™ services are designed to initiate Phase I trials quickly, meaning the ability to obtain the necessary safety and efficacy data to move into Phase II, ensuring proof of concept. This service accelerates drug development timelines moving drug candidates forward using a mix of PCI's expertise and time-tested processes including Just-in-Time (JIT) manufacturing, PIC/PIB services, import/export & permitting of drug products and custom kit design.

Just-in-Time (JIT) Manufacturing for Early Phase Studies

PCI's JIT aseptic and non-sterile manufacturing services support early phase adaptive clinical study designs by reducing drug overage to around 5-10% as opposed to the more expected 50-100% using traditional manufacturing programs. PCI's licensed GMP facilities in Melbourne, Australia are home to our JIT manufacturing services. Our primary focus during manufacture is API conservation and environmental control, with our team verifying that qualification of our GMP processes meet microbiological requirements to ensure safety for clinical use.

Drug overage reduction



Why PCI Melbourne, Australia?

PCI Melbourne offers specific expertise in the early phase processes and operations required including JIT manufacturing, maximizing dosing flexibility to secure stability and efficacy data.

In addition, Australia has become a preferred destination for Phase I trials based on:

- The R&D Tax Incentive of 43.5% rebate for eligible companies
  - overseas clients with less than $20 million AUD aggregate turnover or subsidiaries being eligible to claim this rebate
- The short Clinical Trial Notification (CTN) scheme – approval as little as one week following Human Research Ethics Committee (HREC) review
- The ability to dose patients between 6 and 8 weeks from submission of IRB to HREC
- The ability to access trials in the absence of a full CMC package
- The ability to use data procured in Australia for Phase II IND applications
- Phase I trials being exempt from regulatory inspection
  - PCI's facilities are TGA-licensed GMP facilities
- Multiple Phase I units in Australia being co-located in tertiary teaching hospitals
- Access to world class educational institutions promoting collaborative research.

** Clinical supply CMC characterization and stability studies.*

"Our decision to execute early phase trials in Australia has significantly accelerated our timelines. The combination of Australia's favorable regulatory environment and PCI Melbourne's JIT manufacturing services has contributed to the time savings."

Eric J. Daniels MD, MBA
Co-Founder & COO, Okogen

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