ACCELERATE INTO EARLY PHASE TRIALS
Early phase safety data is key to determining next steps in drug development.

speed to study™ accelerates your trial while maximizing flexibility so you can get the data you need faster.
Speed to Study™ Introduction

Pharmaceutical companies need to streamline early phase development to establish proof of concept, efficacy, and stability of their drug candidates quickly and efficiently. PCI’s Speed to Study™ services are designed to help companies maneuver complex trial designs with maximized flexibility and speed.

We have invested in global teams, sites, and resources to provide you with time-tested phase-specific processes, operations, and the experts you need to get your early phase studies off to a running start.

Speed to Study™ services are designed to initiate Phase I and II trials quickly so you can get the necessary safety and efficacy data. It accelerates drug development timelines, and moves your drug candidates forward.

PCI’s Speed to Study™ services increase the likelihood of meeting first patient-in dates, which is a crucial milestone. Guiding a compound quickly through clinical trials provides priceless data to prioritize which drug candidate should be pursued and which ones should not.

A culture of speed, expertise, and flexibility is key to getting early phase studies started quickly and on the right foot. In the hands of the right people practiced in the manufacture, packaging, labeling, and global distribution of early phase studies, you’ll get your trial started faster with the flexibility to adjust for unforeseen changes.
Speed to Study™ Services Overview

**PHASE I**
- Formulation Development
- JIT Aseptic Manufacturing (syringes/vials/infusion bags)
- Non-Sterile Phase I Manufacturing, including JIT
- Blinding Manufacture
- Analytical Development
- Analytical Testing & Stability Services
- Phase I Packaging and Labeling
- Storage and Distribution
- Regulatory Support

**PHASE II**
- Formulation Development & Optimization
- Dosage Form Process Optimization
- Aseptic Manufacturing (syringes/vials/infusion bags)
- Non-Sterile Phase II Manufacturing
- Comparator Sourcing
- Analytical Testing and Stability Services
- Blinding and placebo manufacture
- Phase II Packaging and Labeling
- Storage and Distribution
- Regulatory Support
Drug Development

Our comprehensive service offering includes early stage formulation and analytical development, API capsule and oral dose filling, compatibility and in-use stability testing, scale-up and process validation, technology transfer and phase-specific validation.

Our strength lies in the integrated nature of our services, combining formulation development and analytical services with clinical trial supplies.

At PCI, we work with you to optimize the process and ensure that regulatory hurdles are minimized and efficient routes to clinic are delivered for potent and non-potent molecules. We are able to offer drug product development services for a variety of dosage forms including:

- Tablets, capsules and powders
- Gels, creams and ointments
- Liquids, solutions, suspensions and emulsions
- Suppositories and pessaries
- Powder blends for reconstitution
- Sterile injections
- Infusion inhalation
Just-in-Time Manufacturing for Early Phase Studies

When you have limited dose strength data or limited API for your clinical trial, consider using Just-in-Time (JIT) manufacturing services to collect safety and pharmacokinetics data without sacrificing quality. It maximizes your dosing flexibility by not committing your drug supply to a few finite dosing options.

PCI’s JIT manufacturing services support early phase adaptive clinical study designs by reducing drug wastage down to only 5-10% drug overage, compared to 50-100% drug overage using traditional manufacturing programs. JIT manufacturing is an effective method to handle clinical supplies that have minimal CMC data, as it allows you to take advantage of your drug product’s limited shelf-life stability.

PCI’s licensed, GMP facilities in Melbourne, Australia house our JIT manufacturing services. Our primary focus during manufacture is API conservation and environmental control, and our team verifies that the qualification of our GMP processes meets microbiological requirements to ensure safety for clinical use.

We utilize single-use, disposable technology for our aseptic processes, which reduces the risks of cross contamination and enhances sterility assurance.

**Drug overage**

<table>
<thead>
<tr>
<th>Traditional Manufacturing</th>
<th>JIT Manufacturing</th>
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<td>50-100%*</td>
<td>5-10%*</td>
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*Clinical supply CMC characterization and stability studies

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**Key aspects of our JIT Phase I Aseptic Processing include:**

- Single-use aseptic processing for Phase I
- Bulk formulation manufacture
- Double filtration to ensure sterility
- Short product expiry (24-72 hours)
- Sterility and endotoxin testing
- Small batch aseptic vial and syringe filling
- Per cohort IV infusion bags
- Media fills and process verification
- Grade B filling suite with Grade A laminar flow
- HEPA filtered pass throughs
Analytical Services and Stability

PCI Clinical Services and our partners offer best-in-class and fully GMP and ICH compliant equipment enabling our teams to perform simple ID testing and analytical method transfers, through method development and validation, to EU product release and ICH stability testing, ensuring data reliability and regulatory compliance.

Stability Testing and Storage Stability studies are an essential component of pharmaceutical development, allowing evaluation of active pharmaceutical ingredient (API) stability or drug product stability under the influence of a variety of environmental factors. Having early, comprehensive and reliable stability data can be key to moving your trial into future phases quickly and efficiently.

Analytical services are offered on a stand-alone basis or in conjunction with our clinical trial and QP services to facilitate a seamless transmission through the drug development cycle.

Our services include:
- Analysis of dosage forms, our laboratory provides data to support new drug applications and development dossiers
- Protocol guided method development and method validation
- Chromatography by HPLC/UPLC
- GC including a range of columns and electrochemical detection
- Disintegration and dissolution testing using USP I and II apparatus
- Spectroscopic analysis including UV/Vis, Fluorescence and FTIR
- Physical testing including particle size determination
- Sterile and non-sterile microbiological testing
- Real-time, accelerated and in-use stability testing
- Custom testing
- Management of subcontracted testing
Custom Kit Design & Manufacture

PCI’s in-house custom kit design and manufacture services can save up to three weeks of outsourcing time while still providing you with a custom solution for your early phase trials.

PCI provides unique services in the area of package development by offering extensive resources from design to commercialization. Three dimensional modeling and in-house prototyping capabilities facilitate rapid prototype design and development. This allows for expedited response and efficient concept generation to enable Speed to Study™ for clinical products.

We also produce short runs of cartons and inserts in-house. All of this results in better designs and significantly shorter lead times to first patient-in kit shipments.
Our scalable packaging systems meet the specific needs of each unique study and the investigational product. Our sites also manage comprehensive studies that require product blinding and over-encapsulation.

Our secondary packaging facilities feature cutting edge technologies that provide solutions for precise assembly and release of patient kits for global studies.

At PCI our philosophy is to employ and maintain best-in-class equipment and technologies. This investment ensures robust packaging solutions for each application and project scope, including manual, semi-automated, and fully automated technologies. Our ultra-modern packaging environments accommodate product needs for light and oxygen sensitivity, temperature controls supporting cold chain management, and low-humidity conditions. The versatility of equipment platforms offers technological solutions for each trial, regardless of scale.
Our comprehensive packaging service includes:

- Package design and development
- Temperature controlled facilities from controlled ambient (15-25°C) to ultra cold chain (-196°C)
- Support services including QP services and product release

Package types supported include:

**Primary Packaging**
- Bottles
- Tubes

**Secondary Packaging**
- Labeling for parenterals and injectables
- Blisters
- Tyvek blistering for parenterals
- Pouches
- Device assembly
- Cartoning
- Kitting
- Child resistant and compliance prompting packaging
- Overwrapping and pouching
- Walleting
- Expiry date extension and over-labeling
- Just-in-Time labeling
- Potent compounds
- Hormones, penicillins, animal health
- Allergens
- Controlled substances
A core part of our service is the development of detailed global supply chain strategies to keep sites supplied with product, while optimizing the supply chain.

The key to any successful clinical trial is having a robust, responsive and efficient logistics plan to enable consistent global supply. At PCI we work with our clients to develop a tailored and dedicated service which meets the needs of their trial requirements whatever the size or global reach. Our dedicated teams of logistic experts across our global geographic touchpoints are able to handle assembly, dispatch and receipt as well as provide a full evaluation and reconciliation of returns to ensure complete accountability and appropriate chain of custody throughout the trial life cycle.

Global Reach

PCI offers over 30 years experience in the storage and distribution of clinical trial materials, effectively storing and shipping thousands of patient kits to over 100 clinical trial countries across the world, across developed and emerging market geographies.

Cold Chain Expertise

PCI is a market leader in the provision of cold chain management services and has extensive capacity and unrivaled expertise to accommodate our client’s refrigerated and frozen storage and distribution requirements.

Our extensive cold chain storage areas are all fully validated, continuously monitored and alarmed providing different storage temperatures, from Controlled Room Temperature (CRT) (15-25°C) down to -196°C. The breadth and quality of our service offering, from one-off samples through to clinical supplies, makes us highly flexible and responsive to every client’s needs.

Our expertly trained and experienced associates handle thousands of temperature sensitive global shipments each year. Well versed in the challenges of global cold chain distribution, PCI understands the specific requirements for
each drug project and utilizes an integrated and trusted global supply chain. PCI utilizes cutting-edge validated shipping technologies and a proven network of fully audited international couriers and depot network.

We are not only qualified to collect, store and deliver clinical trial and pharmaceutical products, we can also provide the collection, storage, return and reconciliation of patient samples including blood, urine and tissue.

We pride ourselves on our flexibility and where a specific requirement is needed we partner with customers to create a bespoke offering at custom temperatures.

PCI has the facilities to store and ship both controlled and dangerous goods throughout the world.
Why Choose PCI for Your Early Phase Studies?

Across our global network, we have developed phase-specific processes to deliver scalable solutions to your early phase clinical supply management needs. Our continued investments in industry-leading technologies and our people allows PCI Clinical Services to offer unparalleled expertise in clinical manufacturing, packaging, labeling, storage and distribution that will get your drug into early phase trials faster without sacrificing quality.

Early phase trials in particular require highly flexible and reliable processes in clinical supply management, as the number of unknown variables is usually higher. PCI has developed agile managerial and operational systems built to accommodate ever-changing clinical project requirements and fast turnaround times without sacrificing quality.

Everything from our manufacturing processes to our quality systems is designed to help you initiate your studies quickly, so you can get complete safety and efficacy data and accelerate your drug development process.
Why Australia?
PCI Melbourne has the early phase expertise, processes and operations needed, such as JIT manufacturing, to maximize the dosing flexibility needed to secure solid stability, safety, and efficacy data. On top of this, Australia has become a top destination for Phase I trials due to:

- R&D Tax Incentive – 43.5% rebate for eligible companies. Overseas clients with less than $20 million AUD aggregate T/O set up subsidiaries to claim rebate
- Short Clinical Trial Notification (CTN) scheme – approval as little as 1 week following Human Research Ethics Committee (HREC) review
- Patients can be dosed 6-8 weeks from submission of IRB to HREC
- Access to trials in the absence of a CMC package
- High diversity of available patient populations
- High concentration of research hospitals
- Data procured in Australia can be used for Phase II IND applications
- Phase I exempt from regulatory inspection (PCI’s facilities are TGA-licensed GMP facilities)
- Multiple Phase I units in Australia are co-located in Tertiary teaching hospitals
- Access to world class educational institutions which promote collaborative research

Customer Testimonial
“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 this time savings.”

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