proSciento®

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# Investigational Product (IP) Management for Metabolic Clinical Studies

## ProSciento's Pharmaceutical Services Team Provides Guidance Through the Complexities of IP Management

ProSciento has a dedicated Pharmaceutical Services (PS) Group that oversees investigational product (IP) management and related specialized services (Table 1) for multicenter, multinational metabolic clinical trials for biopharmaceutical clients worldwide. The PS Group consists of pharmacists and researchers with longstanding expertise in clinical research and stable isotope tracer studies and is headed by Jiale He, MD, PhD, a pharmacologist and internal medicine specialist and a trusted advisor for study sponsors as a member of ProSciento's scientific team for more than a decade.

**TABLE 1: PS GROUP SERVICES**

| IP Management Services | Additional Specialized IP Services |
|---|---|
| Full-scope IP management by ProSciento's PhD pharmacologist and pharmacists | Stable isotope tracer studies, e.g. D-Glucose (6,6-$D_2$), sodium acetate (1-13C) |
| IWRS/EDC system IP management | Study design and protocol contributions |
| Drug depot vendor management - import, export, receiving, inventory, storage, distribution, disposal | Specialized receiving/distributions (cold chain, biologics, hazardous materials etc.) |
| Vendor management for drug packaging and labeling | Drug manual creation |
| Reconstitution/compounding per USP guidelines | Management of long-term retention samples for bioequivalence studies |

### ProSciento's Scientific Expertise is a Differentiator

ProSciento's science-driven approach to IP management differentiates the specialty clinical research organization (CRO) from other CROs, which often take a more tactical business stance. Typically, CROs use project managers who may have limited knowledge of drug management. In contrast, ProSciento looks at the IP holistically as a product moving along the development continuum with a team of experts providing oversight of IP management, which is of particular importance for early-stage development.

**FACILTITY RESOURCES**

State-of-the-art USP 797/800 **clean room** (positive/negative pressure/ante room)

**24/7** storage temperature monitoring and alarm system

**Secure,** controlled access drug rooms

**PROSCIENTO IP MANAGEMENT TRACK RECORD**

IP management for **200+** clinical studies

**5,000+** prepared doses/year

**Drug depot** management to sites across the US

# Investigational Product (IP) Management for Metabolic Clinical Studies

## IP Management and Drug Depot Vendor Management for Multi-Site Studies

ProSciento's PS group has provided IP management for more than 200 clinical studies for study sponsors from more 11 countries. ProSciento also provides seamless integration with drug depot services for IP distribution for multi-site clinical trials. Driving this effort is the PS group's in-depth knowledge of the shipping/storage logistics for different types of drugs and guidelines of US and international regulatory agencies.

The PS group also handles third party activities, namely completing documentation for drug import and export for brokerage firms and contracting with good manufacturing facilities (GMP) for formulating, packing, and labeling of IP. In addition, once studies begin, ProSciento delivers real-time, exportable online reports and provides a dedicated e-mail and telephone Help Desk for end users.

These expansive capabilities are particularly advantageous for small to mid-sized biopharma and biotech companies that lack the resources to address the many elements of product development. In those instances, sponsors frequently seek out ProSciento's PS team early on, sometimes starting with a product in powder form that needs to be compounded into an oral dosing formulation so first-in-human studies can begin. ProSciento routinely performs Good Clinical Practice compounding in compliance with United States Pharmacopeia (USP) guidelines for sterile[1], and non-sterile preparations[2], quality assurance[3], compounding for Phase I investigational studies[4], and more. Table 2 describes a complex compounding study for a small biotech company looking to begin first-in-human studies.

**TABLE 2**

### Case Study: Diabetes Clinical Study with Complex Compounding IP Component

A small biotech company seeking to develop a diabetes therapy contracted with ProSciento to compound its powder into an IP for a phase I first-in-human study involving 50 subjects.

| |
|---|
| This was a new drug preparation process, so the Pharmaceutical Services (PS) group worked with the sponsor from the very beginning—step-by-step—to guide them in selecting the right equipment to use, the right timing for preparation, and the optimal temperature conditions. These processes resulted in ProSciento creating a highly detailed drug manual, per USP standards. |
| The compounding for this specific IP required overnight incubation and approximately 3 hours to compound, a process that included over 10 steps. |
| Multiple doses were prepared in ProSciento's USP 797 standard clean room. |

## Detailed Knowledge of Isotope Tracer Studies

For metabolic studies, diabetes in particular, isotope tracer infusion studies play an important role in the evaluation of the IP. In the US, few CROs have the expertise to conduct tracer studies, requiring them to outsource this function.

ProSciento's PS group is highly skilled at conducting isotope studies, with single and dual tracers, for early phase clinical trials. Moreover, ProSciento has an established network of GMP facilities that manufacture tracers, which is critical for timeline, budget and tracer access considerations as the process to produce a single batch for a clinical trial can take six to 12 months.

Table 3 describes a dual tracer study for a mid-sized pharmaceutical company that involved managing numerous outside vendors, cold chain shipping logistics, and complicated compounding procedures, all on a limited budget.

**TABLE 3**

### Case Study: Dual Tracer Study

A mid-cap pharmaceutical company sought out ProSciento to manage all aspects of a complicated dual tracer phase I diabetes study. With a short timeline, and a limited budget, ProSciento ordered the raw tracer material: [1-13C] sodium acetate, and [6,6-2H2] glucose, and performed the following steps:

| |
|---|
| Managed **7 vendors**: 3 specialty suppliers, 3 specialty labs, and 1 contract manufacturing organization |
| Helped to manage the manufacturing proposal, the batch record, quality assurance/quality control, certificate of analysis, etc. as there was no commercial tracer solution available |
| Compounded the tracers separately in ProSciento's USP 797 clean room using a 28-step sterile procedure |
| Used cold chain shipment logistics for tracer drug sample collection |
| Developed an assay to analyze the samples |
| Created a detailed drug manual |
| Submitted a final report, and managed tracer material destruction |


1 United States Pharmacopeia. Pharmaceutical Compounding – Sterile Preparations. Available at: https://www.usp.org/compounding/general-chapter-797. Accessed January 28, 2021.

2 United States Pharmacopeia. Pharmaceutical Compounding – Nonsterile Preparation. Available at: https://www.usp.org/compounding/general-chapter-795. Accessed January 30, 2021.

3 Quality Assurance in Pharmaceutical Compounding. 2012. Available at: https://www.in.gov/isdh/files/USP1163_Quality%20Assurance%20in%20Compounding.pdf. Accessed January 30, 2021

4 United States Pharmacopeia. Compounding for Phase I Investigational Studies. Available at: https://www.uspnf.com/notices/compounding-phase-i-investigational-studies. Accessed January 30, 2021.




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