Case Study: Preventing Professional & Duplicate Participants in Neuroscience Clinical Trials – Portfolio Support for a Neuroscience Focused Biotech Sponsor

Background:

A small biotechnology company focused on psychiatric and neurological disorders partnered with **Verified Clinical Trials (VCT)** to enhance **subject safety, data reliability, and study validity** across its entire portfolio.

Given the **subjective nature of psychiatric endpoints** and the **vulnerability of neurological populations**, this sponsor recognized that **professional and duplicate participants** represented one of the most serious, yet under-recognized, risks to trial success.

Over a four-year collaboration, VCT supported **nine studies** (four Phase 3 and five Phase 1b) covering major indications such as **schizophrenia and Alzheimer's disease** — all areas known for high placebo responses, variable endpoints, and risk of crossover participation.

Scope and Impact:

Across all studies, VCT **verified 3,127 participants** and **prevented >550 protocol violations**, representing a **~18% violation rate** that would have otherwise gone undetected.

Top 4 violations prevented included:

- Dual enrollment attempts (same or different studies) – 185
- Prior investigational product (IP) exposure - 101
- Dual screening attempts (initial and subsequent alerts) - 94
- Washout period violations - 46

Participants frequently **crossed study boundaries**, enrolling in:

- Multiple studies within the **same therapeutic area** (e.g., different schizophrenia protocols), or
- Entirely **different therapeutic indications** (e.g., a schizophrenia and a metabolic study) in pursuit of compensation or treatment access.

Reducing Placebo Response and Study Noise:

Duplicate participants distort neuroscience trial outcomes in several profound ways:

1. **Inflated Placebo Response:**
   Subjects who are on **active drug in one study and placebo in another** can produce a **false appearance of efficacy**, artificially inflating placebo response rates and blurring the true treatment effect. This "carry-over" bias can cause a promising investigational drug to appear ineffective.
2. **Small N, Big Impact:**
   In many neuroscience trials, the **number of participants determining study success is relatively small**. Just a handful of duplicate subjects can **shift results enough to turn a positive study into a failed one**. Preventing even a few such participants through VCT can be the difference between **meeting endpoints and losing an entire program**.
3. **Compromised Safety:**
   Subjects who receive **multiple investigational products across studies or sponsors** face compounded exposure risks. This can create **spurious adverse events** or false safety signals that delay programs or force repeat trials. In some cases, sponsors have been compelled to **abandon promising compounds** because uncontrolled crossover subjects distorted safety and efficacy data.
4. **Cross-Sponsor Contamination:**
   Because **research participants rarely "stay in their lane"**, they often move freely among studies from different CROs and sponsors. Only VCT's **cross-sponsor and cross-therapeutic registry** can identify these hidden overlaps, ensuring **true independence of trial populations** and protecting all stakeholders in the ecosystem.

Through real-time verification at the **point of screening**, VCT prevents these high-impact errors before randomization — protecting both the **statistical integrity** and **clinical safety** of every study.

Participant Personas:

VCT's longitudinal registry not only detects violations but also helps sponsors understand **why** they occur. In neuroscience, two distinct participant personas dominate:

- **Deceptive Participants (Psychiatric Studies):**
  Some individuals deliberately misrepresent medical histories to qualify for multiple studies or maximize compensation. Without objective verification, their self-reported symptom data can **artificially inflate placebo response** and **distort efficacy endpoints**.
- **Desperate Participants (Neurological Studies):**
  In Alzheimer's and other neurodegenerative diseases, participants or caregivers may seek any opportunity for access to investigational therapies. Fearful of receiving placebo, they **attempt dual enrollment** across sponsors or indications — unknowingly creating **confounding exposure effects** that can invalidate results and introduce safety risks.

Results and Outcomes:

By integrating VCT into its screening and enrollment workflow, the sponsor:

- **Eliminated duplicate and crossover participants** both within and across studies
- **Reduced placebo response and data noise**, preserving true efficacy signals
- **Prevented overlapping IP exposure** that could have led to false adverse events
- **Maintained protocol compliance and regulatory integrity**
- **Avoided costly study repeats** and protected long-term program viability

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Conclusion:

Neuroscience clinical trials are among the most challenging in drug development — characterized by **subjective endpoints, small sample sizes, and vulnerable populations**.

By leveraging VCT's **cross-sponsor, cross-CRO, and cross-therapeutic protections**, this sponsor achieved measurable improvements in **data quality, subject safety, and study success rates**.

Without VCT, duplicate subjects remain invisible.

With VCT, sponsors gain a verified, global safeguard that transforms risk into reliability.