RISK MANAGEMENT PLANNING AND
MANDATED POST-AUTHORIZATION STUDIES
Risk Management & Late Phase Studies in Real-World Research

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EXECUTIVE SUMMARY

Complex pharmacovigilance legislation in an evolving regulatory landscape has left drug makers searching for current, efficient, and more meaningful solutions for their drug safety challenges, especially in the post-marketing arena. Companies are seeking expert advice and customized approaches to effectively collect, manage, and analyze real-world evidence for a competitive advantage.

In recent years, post-marketing safety and risk management has witnessed a fundamental shift from safety monitoring to the benefit-risk paradigm with proactive signal detection and periodic benefit-risk evaluation being the key focuses. The FDA has moved from RiskMAP
to Risk Evaluation and Mitigation Strategy (REMS) and required post-marketing studies to collect real-world evidence to support new drug applications (NDAs)/biologic license applications (BLAs) (FDAAA2008). The European Medicines Agency (EMA) introduced the guideline on good pharmacovigilance practices (GVP), which replaced the previous Volume 9A of the Rules Governing Medicinal Products in the EU. The call for collecting and analyzing real-world data to support periodic benefit-risk evaluation of the product warrants developing, evaluating, and adapting proactive measures to minimize critical risks of the medicinal product and improve overall effectiveness.

PRA’s Safety and Risk Management (SRM) and Late Phase Services (LPS) experts provide sponsors with unique strategies they have developed from years of significant first-hand experience in this area. Our global SRM and LPS groups have significant experience identifying innovative solutions to satisfy key regulatory requirements for their individual risk management planning and execution needs. Our integrated team works seamlessly with in-house and sponsor groups (e.g., medical affairs, safety, regulatory affairs, data management, and biostatistics) to:

- Develop strategic and tactical plans.
- Design studies that align with the associated risk management and data collection objectives.
- Effectively implement these studies in the post-marketing world.
- Design, set up, perform, and analyze literature searches for marketed products.

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1 FDA Guidance for Industry - Development and use of risk minimization action plans - 2008

2 Guideline on good pharmacovigilance practices (GVP) Introductory cover note, last updated with launch of public consultation of addendum I to module XVI on educational materials, EMA/239760/2015
POST-APPROVAL: PLAN EARLY FOR THIS KEY STAGE OF DRUG DEVELOPMENT

Proactive planning is key to successful post-marketing risk management execution. By planning for post-marketing and risk management activities early in the drug development process, sponsors can facilitate a greater return on investment and avoid paying for unnecessary activities.

The number and type of patients studied in product post-approval vary greatly from those studied in earlier phase clinical trials (Figure 1). Length of exposure, population, food habits, and non-controlled intake are some examples of factors that can be significantly different compared to clinical trial experience. Post-marketing studies help to identify trends, outcomes, and signals in large “real-life” populations.

Figure 1: Phase IV - An Integral Stage of Drug Development

Per regulations, it is mandatory that sponsors conduct periodic benefit-risk evaluations and effective risk management planning, as well as submit either a Risk Management Plan (RMP, Europe) or Risk Evaluation and Mitigation Strategies (REMS, FDA) to achieve product approval. In addition, more regulatory agencies in the Rest of World (ROW) now require companies to submit risk management planning documents at the time of licensing application. In order to effectively address these regulatory requirements, it is vital to understand how the key agencies (eg, FDA and EMA) define risk management.

According to the FDA, risk management is an iterative process of:

2. Developing and implementing tools to minimize risks while preserving benefits.

4. Making adjustments, as appropriate, to the risk minimization tools to further improve the benefit-risk balance.

The EMA defines a risk management system as a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent, or minimize risks relating to a medicinal product, including assessing the interventions’ effectiveness.

**Strategy and Design Implementation**

PRA’s overall strategy in the design of a product-specific risk management system is to minimize the burden on the key stakeholders, while achieving the program’s stated goals. Using lessons learned and strategies acquired through decades of relevant experience, our SRM and LPS teams collaborate with companies to identify the critical regulatory requirements for successful risk management planning and execution. We take a proactive, global approach to risk management that ensures our teams effectively interact with regulatory authorities and key stakeholders, providing our sponsors with a harmonized approach to pharmacovigilance and risk minimization activities.

**Signal Detection and Safety Profiling**

PRA collaborates with sponsors to create a detailed signal management plan that outlines the tools, processes, and periodicity necessary to conduct signal detection activities. Our risk management experts:

- Select the appropriate signal detection tools.
- Oversee implementation of the qualitative aspects of the index signal analysis.
- Consult with the biostatistician to determine suitable quantitative methods.

To determine the tools required for signal detection, we consider the stage of the product in its life cycle (eg, pre-market or post-market) and the volume of data to evaluate in the signal analysis process. For post-marketing signal detection, the tools typically include:

- Individual case report management
- Periodic literature searches
- Periodic aggregate reports
- Trending reports
- Standard MedDRA queries (SMQs)
- Data mining
In late-phase clinical research, PRA calculates the frequency of adverse events (AEs) and serious adverse events (SAEs), deaths, and serious adverse reactions (SARs) using subject years as the denominator. When the marketing authorization holder (MAH) provides estimated exposure data computed from sales or prescription data, we generate crude reporting rates based on the estimates as a pseudo-denominator. Then, we forward the outputs to the safety physician who reviews them and compares the frequency of AEs and SAEs (or crude reporting rates) with the reference safety information and results of previous reviews. Finally, the physician initiates the signal validation report.

The signal detection process concludes with a meeting for the signal management team to discuss results. The safety scientist is responsible for scheduling this meeting and compiling and distributing reports. Meetings are scheduled at pre-determined intervals, which can be altered as needed (eg, if a potential signal is deemed to require urgent action).

Our signal detection and safety profiling process is displayed in Figure 2.
**Risk Management Planning**

PRA recommends that companies begin working on risk management systems early in the product life cycle (Phase II) by creating a developmental risk management plan (dRMP). At PRA, the risk management planning process starts with the risk assessment and characterization, followed by finalizing a list of “important risks” with the sponsor and creating safety specifications for the medicinal product in the RMP (Figure 3). Then, we perform a structured evaluation of the need for “additional measures” for pharmacovigilance and risk minimization/mitigation other than “routine activities.” After providing the evaluation report to the sponsor, PRA and the sponsor hold detailed discussions to further develop the pharmacovigilance and risk minimization/mitigation plans. PRA then evaluates and presents effective risk minimization measures (RMMs) to mitigate the important risks and drafts the agreed RMMs for submission to the regulatory agencies.

Depending on the nature of risks, therapeutic indication, and level of required intervention, the RMMs may involve standard risk communications (eg, medication guide, patient information brochure, dear healthcare provider [HCP] letters, etc) or advanced elements to assure safe use (ETASU) for addressing the risks. PRA also helps companies answer regulatory queries related to the risk management system and draft tactical plans for implementation and effectiveness evaluation of RMMs with assessment variables and practical timelines, which are included in the licensing application.

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**RMP Activities**

Risk management planning, a global life cycle activity that preserves the benefit-risk balance of the medicinal product, involves:

- Assessing and characterizing risks (safety specifications/safety profiling).
- Monitoring of such risks in the real world (pharmacovigilance planning; ICH E2E).
- Designing and implementing interventions to actively minimize the occurrence of such risks (risk minimization/mitigation).
- Evaluating interventions to confirm they fit the purpose and are effective, and if not, identifying the reason why (effectiveness evaluation).
- Revising and updating the RMP, if warranted, as an outcome of the effectiveness evaluation.

**Figure 3: Risk Management Planning Activities**
Evaluating Effectiveness of the Risk Management System

Regulatory authorities now mandate that MAHs evaluate their risk management plan’s effectiveness (for both EU-RMP and REMS) at predetermined time intervals in a 2-tiered approach: “process evaluation” and “outcome evaluation.”

The evaluation of effectiveness must report whether the individual RMMs and risk management system, as a whole, have been effective and specify if any corrective actions/improvements are mandated. The process evaluation tier involves individual RMMs (and associated implementation process), while the outcome evaluation tier focuses on the risk management system’s overall impact. Effectiveness indicators (EMA) or metrics (FDA) can be classified as shown:

PROGRESS INDICATORS
- Implementations
  - Reach to target audience
  - Use/Uptake in target audience
- Impact
  - Clinical knowledge (clear understanding of risks)

OUTCOME INDICATORS
- Behavioral changes
  - Clinical actions to avoid or minimize important risks
- Reduction in frequency/severity of important risks

During our comprehensive effectiveness evaluation, we perform an in-depth assessment that encompasses the following activities:

- Stakeholder surveys: assess compliance (eg, distribution of the medication guide or educational material) and stakeholder awareness of product risks
- Tracking of product distribution: use of the stakeholder registry or national (proprietary) databases to monitor product
- Compliance audits: establishing stakeholder agreements to produce on-demand proof-of-compliance with program requirements
- Internet surveillance: monitor availability of product outside the program
- MAHs use of standard pharmacovigilance activities: closely monitor AEs of special interest linked to the product’s known safety risks

Mandated Post-Authorization Safety Studies

After granting marketing authorization for a medical product, the regulatory authorities frequently request the marketing authorization holder (MAH) to conduct a post-authorization study. In accordance with EU Dir Art 1(15), this study is classified as post-authorization safety study (PASS) when the main objective is to gather additional safety information, assess patterns of drug utilization, or to measure the effectiveness of a risk minimization activity. Combined with regulations, the EMA (GVP Module VIII) and the FDA (FDAAA2007) increased the pressure on drug makers and moved from post-marketing commitments to post-marketing requirements for PASS, inducing the MAH to consider and implement multi-regional PASS.
In Europe, the RMP specifies the necessary steps and processes needed to conduct a PASS. According to DIR Art 107m (1), Regulation (EC) No 726/2004 (REG) Art 28b, these studies should be conducted according to the following provisions:

- DIR Art 107m-q and Commission Implementing Regulation (EU) No 520/2012 (IR) Art 36-38 for PASS initiated, managed, or financed by a marketing authorization holder pursuant to an obligation imposed by a competent authority, which includes:
  - Studies imposed as an obligation in accordance with REG Art 10 and Art 10a and with DIR Art 21a and Art 22a (category 1 of studies in Module V).
  - Studies imposed as a specific obligation in the framework of a marketing authorization granted under exceptional circumstances (GVP Module V, V.B.9.4) also reflected in Annex II to the marketing authorization.

**Protocol Design and Development**

Detailed guidance on protocol design and development is available from different sources, including EMA Guidance3, European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Guide4, and International Society for Pharmaceutical Engineering (ISPE) Guidelines5.

Pending the main objectives, a PASS is generally observational in nature, though may involve a different study design, when necessary. PRA’s specialists (including late-phase ENCePP members, as well as medical affairs, safety, and biostatistics professionals) have developed the following study protocol considerations for PASS:

- Define the milestones for study progress and reporting, aligned with initial agreement and development of strategy to respect milestone timing
- Develop the study rationale, including the concerns or questions leading to the study
- Determine the study’s overall goal per requirements and translation of this goal into specific measurable objectives
- Describe the source and study population adequately and appropriately with regard to the study research question and objectives

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3 Guidance for the format and content of the protocol of non-interventional post-authorisation safety studies EMA/623947/2012
4 The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), Guide on Methodological Standards in Pharmacoepidemiology EMA/95098/2010 Rev.3.
• Provide detail about the methods used to collect, register, and control the necessary information

• Detail the rationale for the study sample size and statistical analysis in terms of the specific objectives of the study

PRA employs the above considerations for non-interventional PASS based on official guidelines and recent experiences in protocol evaluation by regulatory authorities.

**Non-Interventional PASS Implementation and Execution**

Whether epidemiological or clinical, the studies’ results and findings depend on data quality. Although quality data is essential to any research project, the most frequent approach to define data quality is to consider 2 principles that are the pillars for any type of research: data completeness and data validity.

This general consideration is also applicable to prospective non-interventional PASS, with the limiting factor that medical procedures and assessments cannot be mandatory. By applying this constraint to real-world research, PRA has developed an approach based on the implementation of the appropriate oversight to validate that existing data aligned to routine practice are correctly reported according to the study protocol.

Our main objectives are to:

• **Guarantee patient protection**: make sure patients are appropriately informed, their confidentiality is maintained, and the medical practice is based on the best benefit to the patients and not modified by their participation in the study

• **Avoid unreported data and minimize errors**: all existing data of interest have to reflect the reality—motivating and maintaining awareness of sites and patients are critical to reach this objective

• **Ensure that missing data are unavailable and not unreported**: it is unrealistic to expect that all data as defined in the study protocol will be available even if the protocol matches the standard of care; routine practice is subject to uncontrolled parameters such as time, instruments’ availability, and conflict of priority impacting the existence of the data

We further support this approach with proven and effective processes for delivering high-quality study data gathered by expert physicians through efficient collection and review.
Physician Selection

PRA recommends establishing a physician selection plan to minimize any potential biases in the selection of physicians who are prescribers of the medicinal product. When the prescriber selection process is fully documented in the Physician Selection Plan, only a summary has to be included in the protocol and in the final study report’s appendix.

During the physician selection process, PRA:

- Identifies the product prescribers who use a data source not specifically set up for the study, but simply record prescribers for other purposes.
- Culls initial prescribers from databases in a randomized manner to minimize bias and to qualify them in the order of responses and according to the predefined distribution (e.g., location and profile).
- Ensures only limited information is provided at the time of the contact, as knowledge of study objectives may impose a change in prescribing behaviors of the selected physicians or may lead to “non-compliant prescribers” declining participation in the study.

EDC Tools

Selecting the appropriate EDC tools helps to ensure data completeness, reduces site burden, and maintains site motivation. Although many EDC systems are available and can support the needs of non-interventional PASS, PRA considers some critical characteristics to determine or support our sponsors in defining the most appropriate tools. These include:

- Flexibility of the electronic data collection (EDC) system to meet the needs related to the fluctuation of data availability inherent in real-world research
- User-friendly, intuitive, role-based workflows that avoid a long list of data per screen
- Combined system supporting medical electronic Case Report Form (eCRF) and ePRO in one database for mitigating long-term follow-up and facilitating the review

Risk-Based Monitoring

Risk-based monitoring (RBM) can be an invaluable approach to ensure data validity when conducting non-interventional PASS. The growing consensus among clinical researchers and regulatory authorities is that RBM is more likely to ensure patient protection and overall study quality and is more effective than the traditional monitoring model of routine visits to all sites with 100% source data verification (SDV).
PRA provides a flexible, guided approach that addresses each phase of sponsor implementation as they transition from 100% source data verification (SDV) to full risk-based monitoring (RBM) (Figure 4 below).

**Figure 4: PRA Adaptive Monitoring Transition Process**

The key to successful adaptive monitoring is our concise design that holistically evaluates each study, determines the necessary organizational structure to support both central and on-site monitoring, and provides the necessary framework to conduct real-time trend analysis.

**Key Steps for a Successful RBM Approach**

1. **Proposal Stage**: The operational delivery director and therapeutic expert (TE) evaluate the protocol using a shortened or “mini” adaptive monitoring assessment tool to evaluate the overall project risks. From this assessment, the delivery director and TE determine an adaptive monitoring approach for the proposal, which includes the amount of on-site SDV that will be performed, centralized data monitoring and reviews, analytic review meetings, and data cleaning strategies.

2. **Evaluation Stage**: Following the proposal stage and additional client discussions on the proposed strategy, the PRA team evaluates the full protocol during the study’s start-up phase using the adaptive monitoring assessment tool. This detailed risk evaluation is conducted at the kick-off meeting.

This evaluation provides the supporting documentation to the study team as well as any regulatory agencies to type and level of monitoring that will be performed and the
ongoing evaluation of analytics and variables that will be used throughout the study to manage or trigger additional monitoring visits or requested changes in the study’s current monitoring schema. The study management scheme is comprised of many components including:

- Frequency of analytic reviews (re-occurring adaptive monitoring meetings) with associated trigger points of key risk indicators (KRIs) identification of protocol key risk indicators.
  - Level of SDR and SDV (Note: not all studies will have a reduction in SDVs). Each study will use what is appropriate based on the needs of that study and the sponsor’s risk tolerance.
  - Type of central monitoring involvement.
  - Monitoring Scheme (targeted, random, escalating, declining, random, tiered, triggered, etc) and rules for escalation.
  - EDC design to support SDV scheme.

After the evaluation phase, the study team documents the proposed solutions in the project plans (eg, monitoring schema, EDC design for SDV, analytic review plans, and ongoing assessment meetings).

3. **Execution Stage:** The study team meets on a reoccurring basis to evaluate current analytics in many areas, including study metrics, safety parameters, data quality, monitoring assessments, and feedback, to determine if additional response plans need to be implemented. For example, 2 sites have an AE rate that is 2 to 3 times higher than all other sites, which may trigger an additional on-site interim monitoring visit (IMV) to conduct source data review on that area. Any major changes to the overall study design may trigger a re-evaluation of the overall monitoring schema. Some examples include: a major protocol amendment, changing the study design, doubling the number of sites, or adding more countries.

_It is critical that documentation is filed regularly so that regulatory reviewers may determine how the study was conducted and how the team performed the proper oversight and management of the study._

**Experience with RBM Approach**

PRA has been utilizing RBM approaches for more than 20 years in our late-phase studies. Our collaboration with sponsors and the RBM community has allowed PRA to help shape the future of RBM policies and best practices while implementing these proven best practices within our studies. We believe that a true adaptive monitoring
strategy provides significant benefits to all studies. Currently, more than 25 of our active phase II-III product registration studies and more than 30 post-marketing studies are currently employing adaptive monitoring approaches at PRA. In addition, 30-40% of PRA’s new request for proposals are requesting an adaptive monitoring schema.

WORKING WITH AN EXPERIENCED PARTNER

PRA’s approach to conducting risk management activities in the post-approval phase involves highly experienced professionals from late phase, regulatory, safety, and other key groups working together under a centralized, global operational model to serve our sponsors.

Our global SRM and LPS teams work seamlessly with different stakeholders (in-house and sponsor) to develop and implement a plan that aligns with the associated project objectives (Figure 5). Our experts are fully trained and highly experienced in delivering the full spectrum of services, enabling them to deliver successful post-approval drug safety solutions.

![Figure 5: PRA’s Expert Pool for Full-Spectrum Services in Global Benefit-Risk Management](image)

Insightful Approaches to Risk Management

We conduct extensive research to determine the appropriate regulatory agency’s current focus on the particular drug class and the effect an RMP will have on the associated stakeholders (prescriber, pharmacy, distributor, and patient/caregiver). Once a risk has been identified, PRA discusses with the sponsor (and the regulatory
Comprehensive Expertise and Services

Furthermore, PRA offers real-world and late-phase research expertise to help guide the design and implementation of high quality research programs. Our goal is to deliver end-to-end life cycle solutions across all therapeutic areas. Our scientific expertise and operational excellence enable our project teams to provide the full spectrum of services necessary to meet each program’s unique objectives, such as safety mandates. Specifically, PRA LPS can address observational PASS with comprehensive solutions based on industry-leading experts, a global reach with local knowledge, a data-driven approach, and intuitive and flexible technologies.

By employing state-of-the-art technologies and approaches, we support sponsors’ projects, while providing insightful access to study data, metrics, and industry-standard delivery models.

SRM Services Provided

PRA provides SRM services during the entire product life cycle. Figure 6 outlines the SRM services that PRA offers. In addition, our SRM services also include literature search services for routine pharmacovigilance (PV), aggregate safety analysis, and endpoint adjudication services for both pre- and post-approval studies.

PRA’s SRM experts also provide the following services to support NDA/BLA/MAA and post-marketing life cycle activities:

• Signal detection and management
• Structured benefit-risk evaluation
• Risk Management Plans/REMS
• Pharmacovigilance planning and implementation
• Risk minimization/mitigation planning and implementation
• Effectiveness evaluation plan for risk minimization/mitigation measures
  ♦ Development and maintenance of PV system master file
  ♦ Automated literature searches storing and archiving all results electronically
  ♦ Generation of search criteria for listings of references and abstracts
  ♦ Expert screening by PV specialists to identify specific citations that are “suspect”
  ♦ Ad hoc or customized literature searches to meet specific needs, (e.g., PSUR reporting)
  ♦ Regulatory reporting on behalf of our clients
  ♦ Concise and timely consultation and communication with clients regarding search findings

**During Product Life Cycle**

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**Figure 6: PRA Safety & Risk Management Services**
Literature Surveillance

Literature surveillance is a mandatory business strategy that reduces risks and costs, increases safety, and enhances value for the MAH by evaluating and managing risk throughout a product’s life cycle, pre- and post-marketing, and keeping marketed products safely on the market.

With increasing public interest in drug safety and new guidelines from the regulators, it is no longer enough to simply collect and report adverse events. Today, MAHs are expected to conduct post-marketing surveillance proactively in order to detect safety signals broadly across all usage.

Medical literature is by far the most effective system for initial detection because case reports are detailed, assessed for quality by reviewers mostly independent from commercial incentives, and open to interested parties. The collaborative output of the 20 largest medical journals in highlighting a new problem by a single case report easily outclasses every other system. Many important adverse drug reactions were shown to be detected and verified by voluntary reporting, predominantly through the literature.

Medical literature is a highly efficient warning system for new adverse reactions and often recognizes rare events and people at high risk. Data published in global scientific literature or presented as abstracts, posters, or communications are an important source of information for MAHs to ascertain ongoing safety evaluation of their medicinal products. The success of searching published literature is measured in terms of precision and sensitivity, not accepting any loss of sensitivity when searching for pharmacovigilance.

All regulatory bodies require screening and analysis of published literature starting from submission until suspension or withdrawal of the marketing authorization for safety or commercial reasons, as noted in the guidelines on pharmacovigilance for medicinal products for human use. The MAH is therefore expected to maintain awareness of possible publications by accessing a widely used systematic literature review and reference database (e.g., Medline, Excerpta Medica, or Embase) no less frequently than once a week. The requirement for literature searching is not dependent on a product being marketed. It is the MAH’s responsibility to organize a systematic search on any impact on the risk-benefit assessment for the drugs they commercialize and to ensure the adequacy of the resources they are using to undertake searches for active ingredients including more than brand names.

Even in the given regulatory framework, MHRA Pharmacovigilance inspections of MAHs showed that inadequacies in the construction of, or process used for, literature searching are relatively common.
PRA acts as an experienced partner for MAHs with clear, integrated processes and accountabilities managing the required weekly literature surveillance by conducting qualified scientific review of international scientific literature (articles, manuscripts, abstracts, and excerpts) according to guidelines from EMA, FDA, Canada, TGA, etc, to ensure complete and diligent product case management, regulatory reporting, PSUR reporting, risk management analysis, and other ad hoc safety reports. Risks are appropriately recognized, assessed, and managed.

PRA has the right governance structure, people, processes, and technologies in place to support effective pharmacovigilance with a dedicated team of experienced information specialists, having either medical, other healthcare, scientific, or IT backgrounds. Either complete product portfolios or parts of it are under continuous surveillance.

Dependent on the client infrastructure, PRA can manage the whole process from weekly search to regulatory reporting or only parts of it. All records are stored and archived electronically for inspection purposes. Our clients will be provided with “Executive Summary Reports” within agreed timelines highlighting search and assessment success as well as brief information about potentially interesting literature. In addition, charts about project progress will keep our clients updated. The whole process follows a strict, but lean, workflow ensuring both performance and quality. Based on strict guidelines, the process is regularly internally audited to deliver the highest quality and identification rates to our customers.

**Safety & Risk Management and Late Phase Services**

PRA’s SRM and LPS groups are global leaders in the design, management, and execution of peri- and post-authorization programs for pharmaceutical, device, and biotech companies. Our scientific expertise and operational excellence enables our project teams to provide a full spectrum of services and flexible approach for all designs:

- Registries: patient, disease, product, pregnancy
- Observational studies/non-interventional studies (NIS)
- Post-authorization safety studies
- Benefit-risk management/REMS
- Post-marketing safety and surveillance
- Health outcomes/health economics
- Quality of life and patient reported outcomes (PRO)
- Post-marketing/regulatory commitment
- Comparative effectiveness research
• Retrospective chart reviews
• Pharmacoepidemiologic studies

Our LPS group has 130+ dedicated employees based in 3 LPS hubs covering more than 60 countries: Horsham, Pennsylvania; Mannheim, Germany; and Singapore. The SRM team has more than 165 employees in 6 drug safety centers: Germany, UK, US, Brazil, and Singapore (Figure 7).

Figure 7: PRA LPS Centralized Management Locations and Drug Safety Centers
CONTACT INFORMATION

For further information on PRA’s approach to risk management and late-phase research, please contact your Business Development Manager or the employees listed below:

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PRA Health Sciences delivers innovative drug development solutions that improve patients’ lives. Our people are passionate about clinical research, working tirelessly to provide quality results for clients. We offer exceptional experience across all phases, therapeutic areas, and a broad spectrum of solutions, ranging from full-service clinical development to our pioneering Embedded model.

With 11,000+ employees covering 80+ countries, we bolster an impressive global presence with keen local insights. Our project teams harness their understanding of local regulations, standards of care, and cultural customs to effectively align our approaches with each study’s unique goals.

At PRA, we love what we do because we are making a difference in the lives of patients and their family members worldwide. Over the years, we have contributed to the development of numerous drugs now available to countless patients. From our scientific and medical experts to therapeutically aligned project managers and monitors, we provide the commitment and expertise needed for today’s complex studies.

To learn more about PRA, please visit www.prah.com or email us at prahealthsciences@prahs.com.