



EPIDEMIOLOGICAL RESEARCH

In the dynamically transitioning pharmaceutical environment,
we provide the most precise and scientifically approved solution for your research



LSK Global PS Epidemiological Research Dept.

Post Market Surveillance, Observational and Post Market Study Experts

LSK Global PS has established Epidemiological Research Department in the year 2010 to provide specialized services such as rPMS (Regulatory Post-Marketing Surveillance/Re-examination Study) and Observational Study (Prospective/Retrospective) for all process.

Understanding the distinctive attributes of non-intervention study and intervention study is crucial for the study management and project team organization of non-intervention studies.

LSK Global PS ER department comprehends the difference between post-market trials from intervention studies and effectively conducts rPMS, Observation studies and or Epidemiological studies.

Target Study

- **Post Marketing Surveillance**
- **Observational study without intervention**
 - Safety study
 - Efficacy study
 - Drug utility research
 - Chart review study
 - RWD study



The Strength of LSK Global PS “Epidemiological Research”

Epidemiological Research Experts

ER Specialists team exclusively responsible for non-intervention study

Project Lead for Study Management and Communication Facilitation

PL (Project Lead) pro-actively leads and manages the study progress

PMP for Effective Project Conduct

Establishment of SMP (Site Monitoring Plan), SAP (Statistical Analysis Plan), DMP (Data Management Plan) for developing systematic project management plan

1. Epidemiological Research Experts

Synergy between Epidemiology Research and Statistics

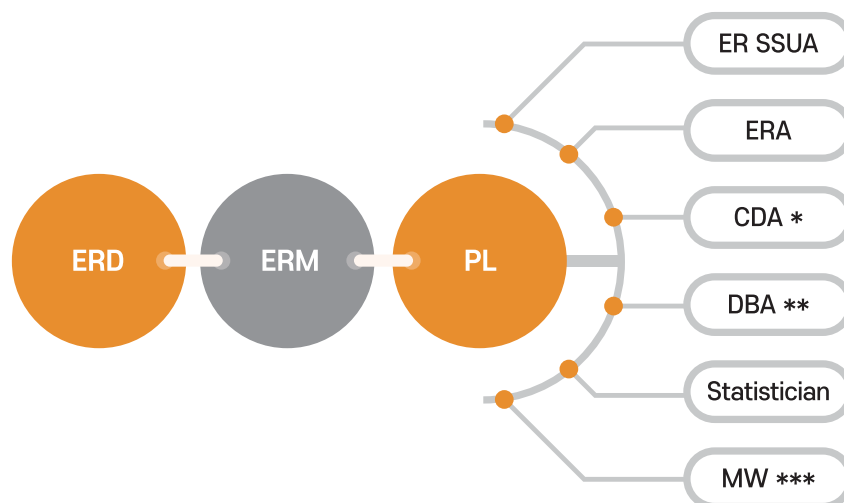
LSK ER department is an affiliated team of STAT/ER division cooperating closely with STAT department.

Collaborative teamwork with STAT team is essential because in epidemiological research a statistical approach for research planning, data analysis, and data interpretation of the final result is imperative.

LSK ER department is consisted of experts with nursing/public health backgrounds which enables a comprehensive understanding of the purpose of the research and project management producing the most scientifically optimized research result.

ER department has developed ER SOPs which reflects different standards from intervention studies to conduct a more suitable and efficient epidemiological research.

• Study Team Organization for Full Scope Service



* CDA: data management of observational studies in CDM HQ (CRF development, DVS, Query issue, Medical coding, DBQC, DBL)

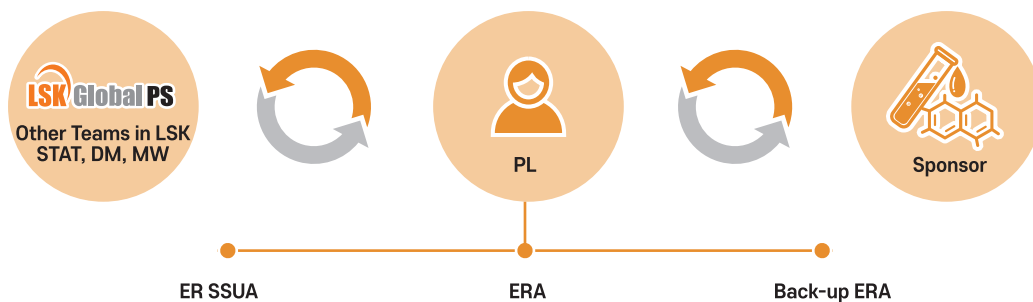
** DBA: system development of eCRF and programming/validation in CDM HQ

*** MW: protocol development and medical writing of CSR in MW team

2. Project Lead for Study Management and Communication Facilitation

Project Management by PL

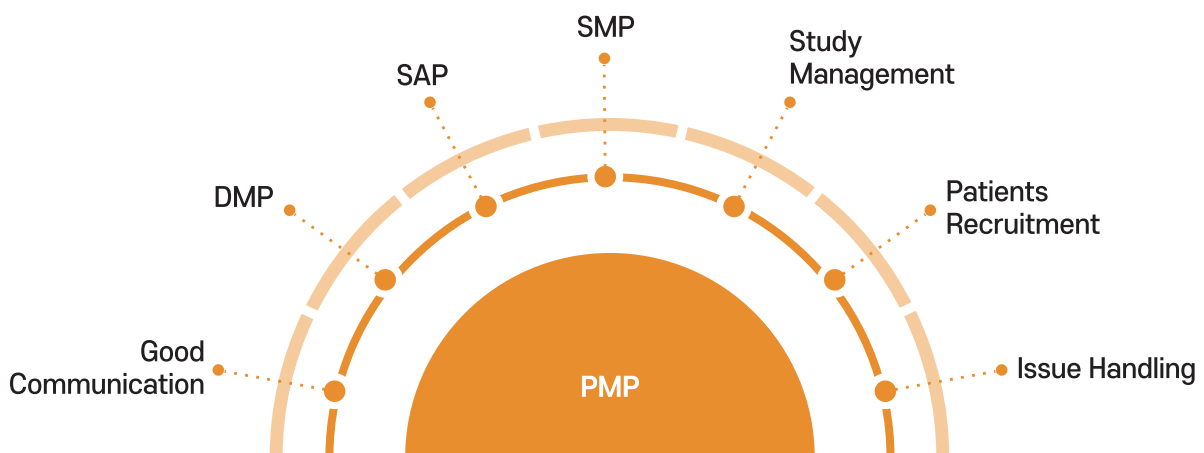
LSK Global PS ER dept. provides PMP (Project Management Plan) development, project management, IRB affairs, site contract, pre-study site visit (PSSV), site initiation visit (SIV), site monitoring, site close visit (COV), query resolution support, and all service that are related to operating epidemiological research. Additionally, study protocol development, data management (DM), statistical analysis (STAT) will be responsible by MW & RES (Medical Writing & Research), CDM (Clinical Data Management), STAT (Statistical analysis) departments and with the cooperation of each professional a full-service epidemiological research is administered.



3. PMP for Effective Project Conduct

PMP (Project Management Plan) is developed for exhaustive project management and along with SMP (Study Monitoring Plan), DMP (Data Management Plan), SAP (Statistical Analysis Plan), a more specific plan is prepared for optimum conduct of epidemiological research.

- Accumulated Research Experience Maximizes the Best Epidemiological Research Planning



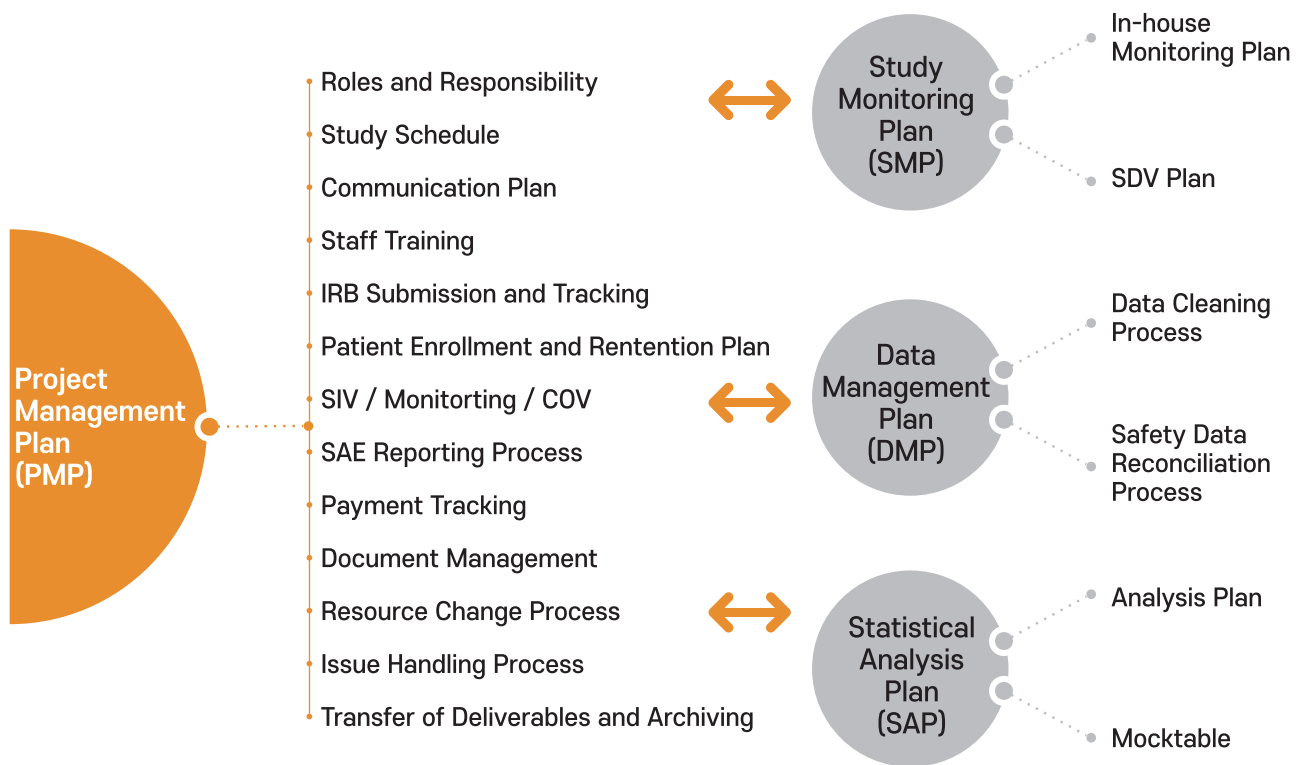
Risk Management



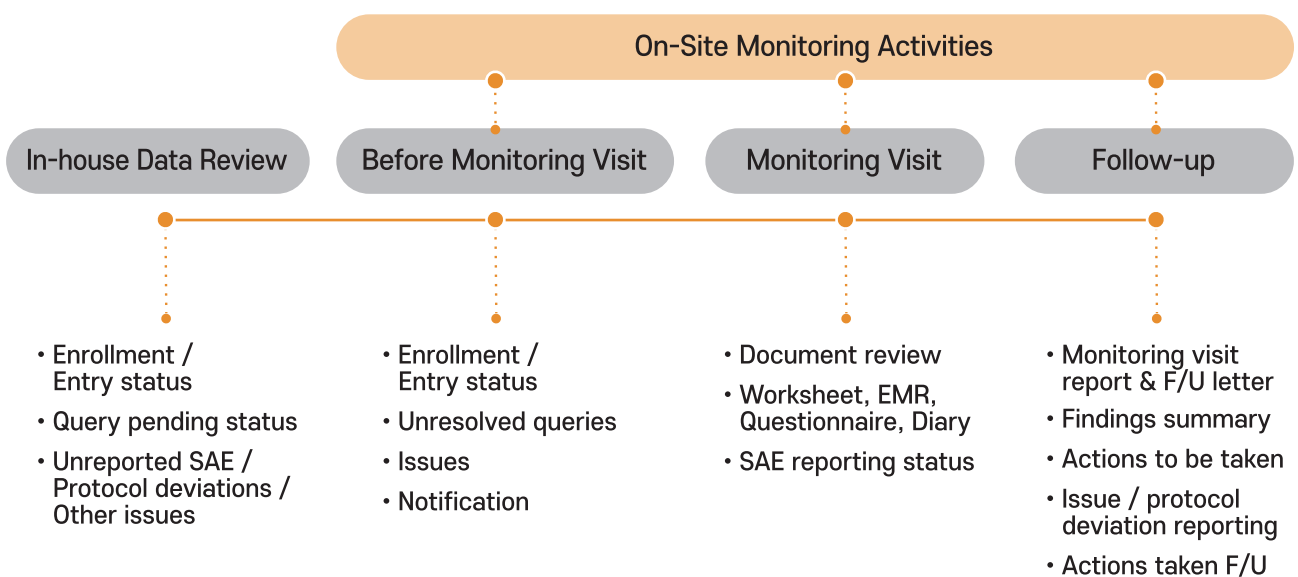
Quality Management



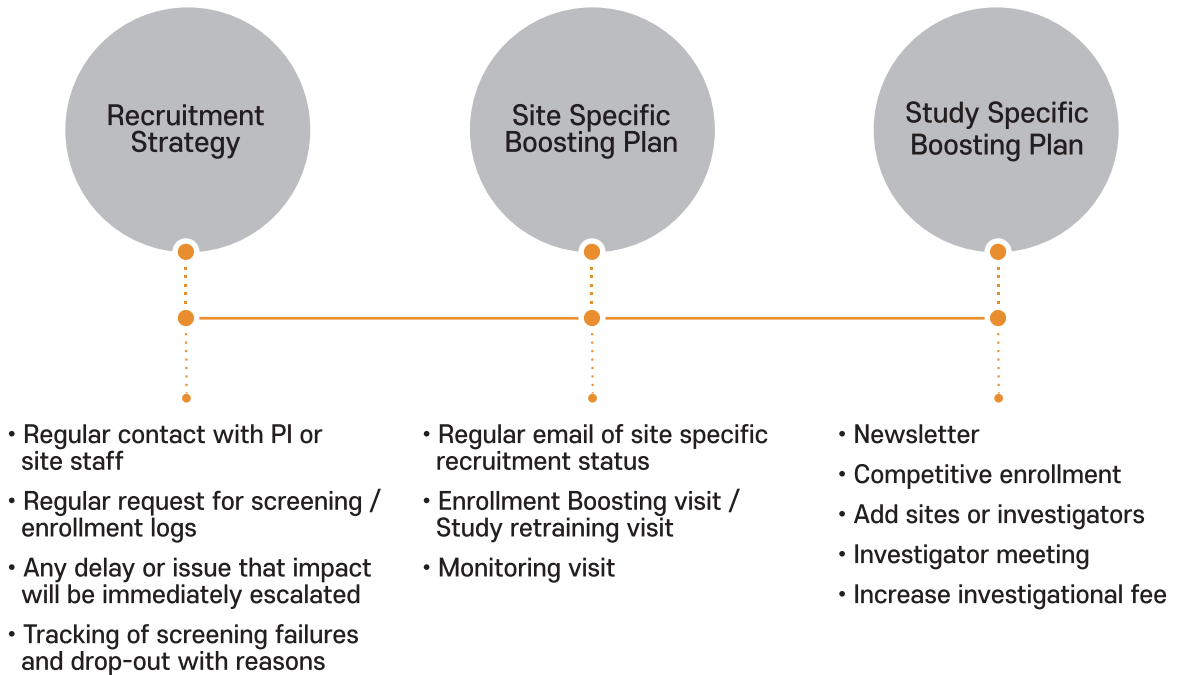
Meet Study Goal



Excellent Monitoring Plan Development for Epidemiological Research



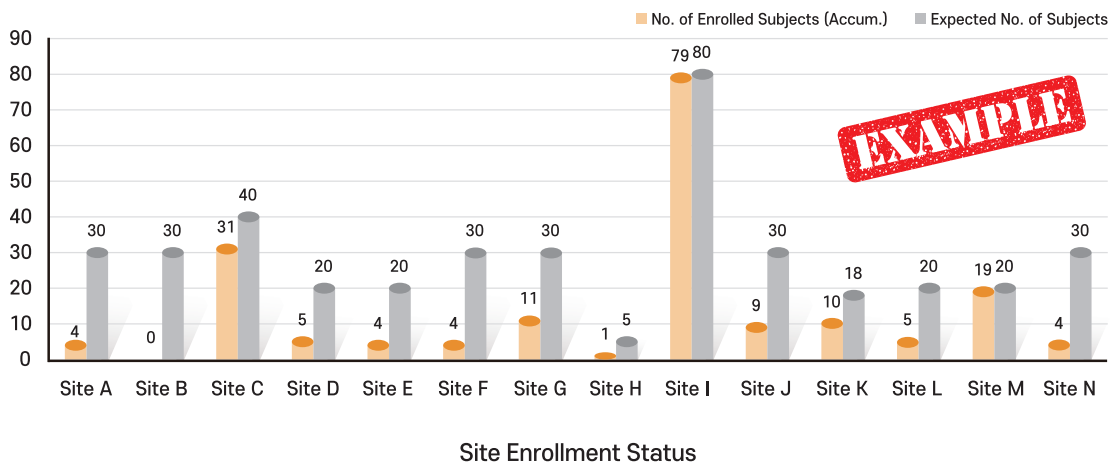
Recruitment Plan



Recruitment Status Reporting

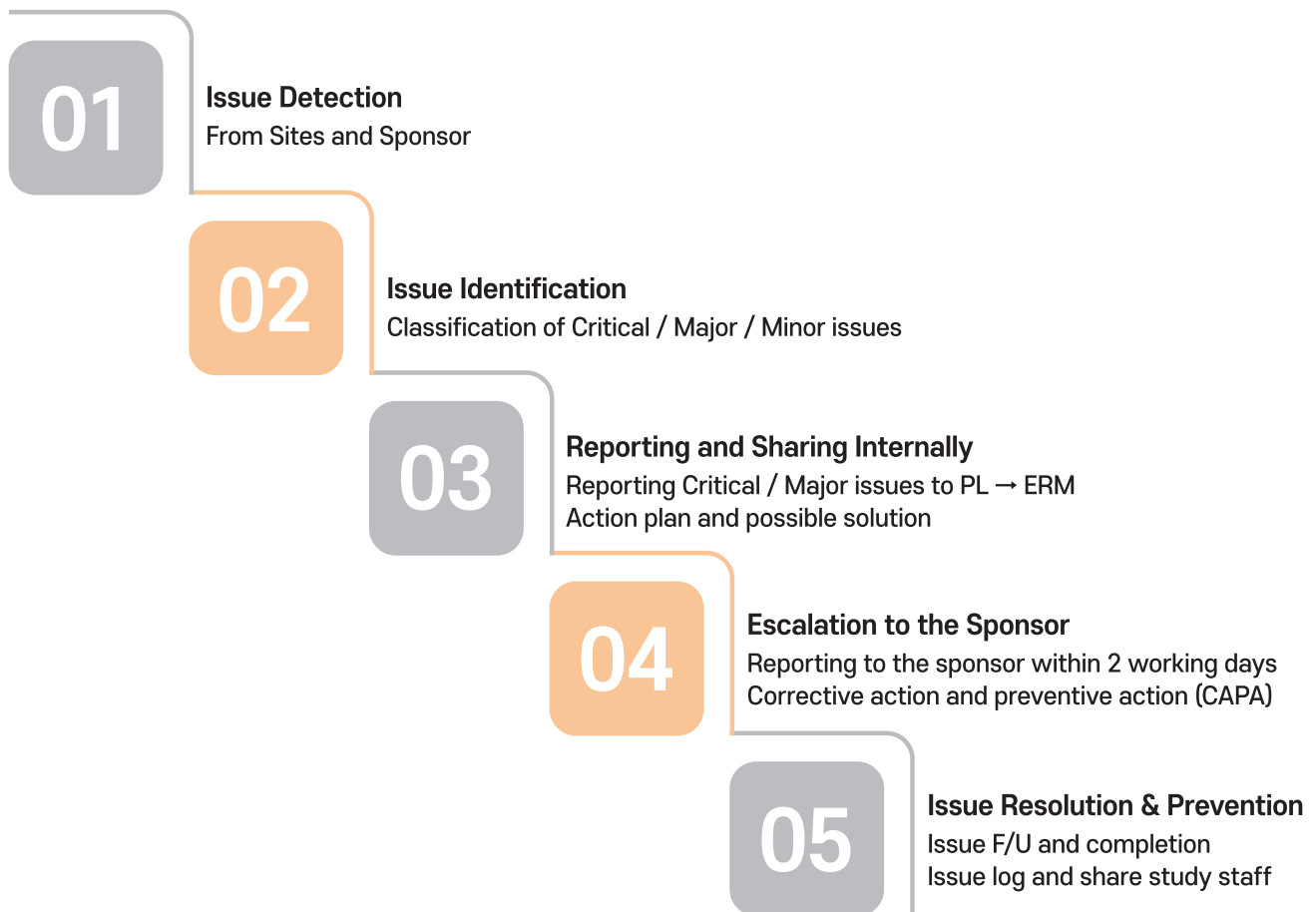
For non-performing sites,

- Identify reasons
- Increase frequency of contact with PI
 - Boosting & Retraining visit / Newsletter & Encouragement email





Issue Handling Process



Risks Prediction



Estimate
Impacts



Define Responses
to Risks / Issues



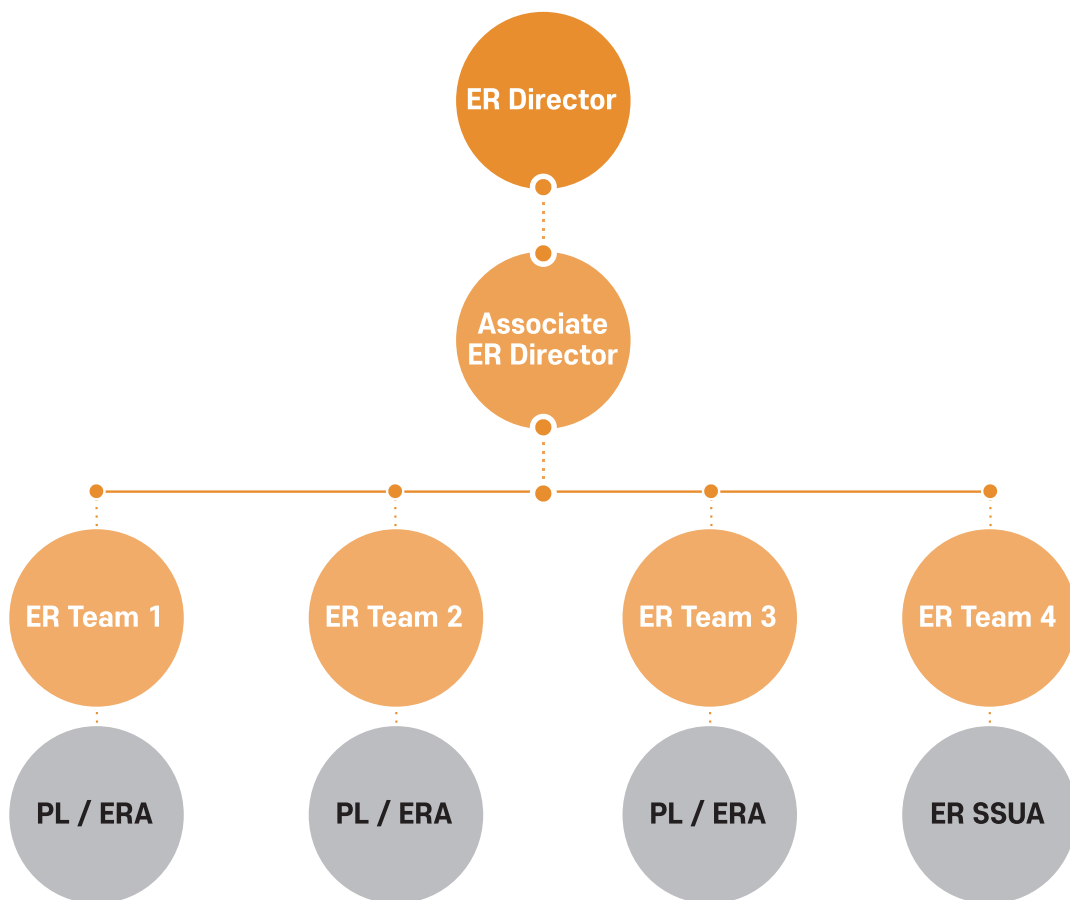
Minimize
Impacts

About LSK Global PS Epidemiological Research Department

“**VISION** | In the dynamically transitioning pharmaceutical environment, we provide the most precise and scientifically approved solution for your research”

1. Organization Structure

ER department is consisted of 4 teams under ER Director and ER Associated Director. ER Team 1, 2, and 3 PL and ERAs are responsible for project management and operation. ER Team 4 SSUA (Site Start Up Associate) handles IRB Submission.





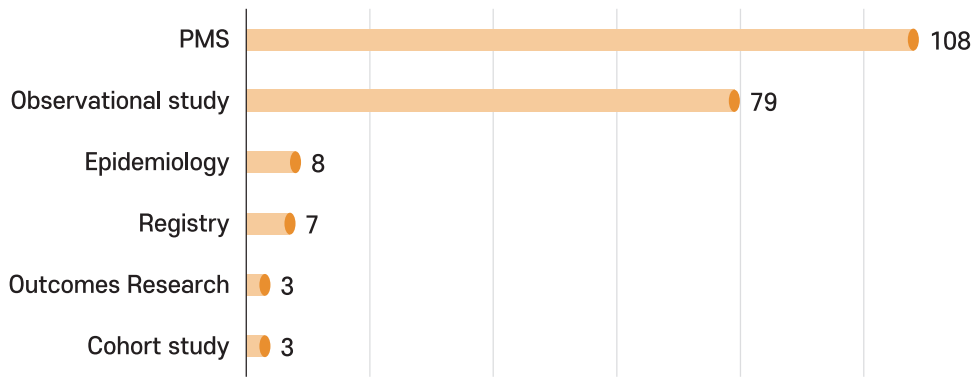
Role	Responsibility	Operation Description
ERM	<ul style="list-style-type: none">• Study overall management• Review of PMP• Review and approval of study materials• Study site co-visit	Study overall Management Site Management (Documents, Monitoring, Issues)
PL	<ul style="list-style-type: none">• Contact person with Sponsor• Preparation of study documents: PMP, issue report, study status report, etc• Study overall management• Study document management	
ERA	<ul style="list-style-type: none">• IRB affairs / Contract support• Site visit (staff training, study initiation, patient enrollment encouragement, close-out, Query resolution, etc)• Site communication• Query resolution support• Study document management	
ER SSUM	<ul style="list-style-type: none">• Contact person with Sponsor about IRB & Site Contract• IRB affairs / Contract management• Overall management of IRB affairs	Study Start-Up Full IRB Support (IRB submission & Site contract)
ER SSUA	<ul style="list-style-type: none">• IRB affairs / Contract support• Site communication• Query resolution support• Study document management	



2. Extensive Experience

NIS Study Type

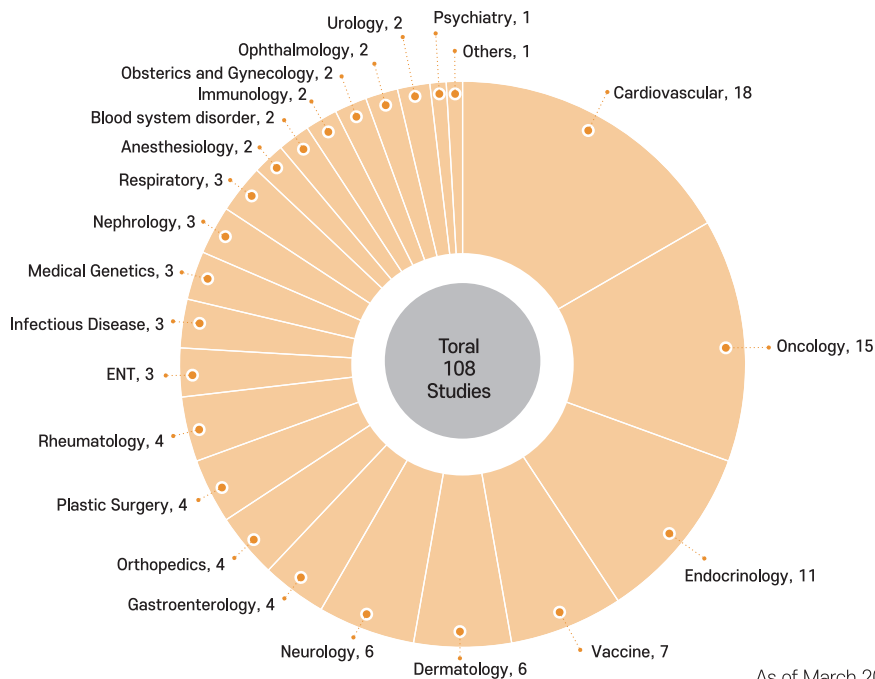
For more than 200 different types of non-intervention project experiences as of the year 2021 March.



As of March 2021

PMS Therapeutic Areas

For more than 108 non-intervention projects of wide range of experienced areas including cardiovascular, oncology, and endocrinology as of the year 2021 March.



As of March 2021

3. High Client Satisfaction

According to our client satisfaction rate survey, the PMS and Observational Studies have received high satisfaction results.

* Evaluation criteria: staff expertise/experience, responsiveness for each milestone and sponsor requests, communication with the Sponsor, compliance with the expected timeline, service cost, quality of the outcome.



Epidemiological Research

“The Best Partner in Bio Pharma Industry”

- 01** LSK Global PS understands that the need and utilization of Real World Data is emphasized in the industry. Along with the ER dept., LSK PV, DM, STAT, and MW dept. professionals will develop research plans and conduct your study using RWD to provide ONE STOP FULL SERVICE for your diverse types of research.
- 02** The drug development environment has rapidly changed after the COVID-19 pandemic and LSK Global PS is capable of quickly adapting to the circumstances and acknowledging the needs of the Sponsors. With 20 years of experience, LSK develops the specific service model and programs for our sponsors for more efficient drug safety data.
- 03** Epidemiological research requires a more extensive amount of expertise and experience in statistical data analysis due to biases and confounding issues that are not considered in intervention studies. LSK Global PS provides a great advantage in epidemiological research design and data analysis with the integrated operation of statisticians and epidemiological researchers.
- 04** Complying with the new guidelines for the re-examination of approved drugs in the year 2022 standards and the rapidly evolving pharmaceutical industry, LSK provides the expertise and transparent research result based on our years of experience in various research areas.





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