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Pharmaceutical Approaches to Enhance RWD Quality and Strengthen RWE in Non-Interventional Studies

Soo Hyun Lee[1], Bo-Ram Park[1], Ha-Yeong Gil[1], and Seung-Hee Jeong[1]

[1] Korea Real-World Evidence Generation Team, Development Japan, Pfizer

INTRODUCTION

Real-world data (RWD) has become increasingly vital in healthcare research, offering insights into patient outcomes, treatment patterns, and disease burden outside the constraints of randomized controlled trials. Non-interventional studies (NIS), which collect RWD without altering standard clinical practice, are particularly valuable for understanding real-world effectiveness and informing regulatory and policy decisions.

However, the utility of RWD depends not only on its relevance but also on its data protection, integrity, and quality assurance. Ensuring these elements is especially critical when dealing with sensitive patient information and when the data is used to generate real-world evidence (RWE) that may influence healthcare strategies.

This study aims to explore the data protection, integrity, and quality assurance aspects of the RWD collected in the NIS.

METHODS

This study focuses on a non-interventional study (NIS) conducted in South Korea to evaluate the burden of Respiratory Syncytial Virus (RSV) infections and associated risk factors in infants and children aged five years and younger, using data from medical chart reviews and patient-reported outcomes (survey).

- **Data Sources:** Medical chart reviews and patient-reported outcomes (surveys).
- **Sample Size:** 59 patients enrolled between December 2023 and February 2024.

RESULTS

- High completeness (>95% for key variables)
- Low missingness across patient records
- Consistent response distributions
- Confirmed accuracy via SDV of EMR
- No systematic errors detected
- Data security and validation ensured through encryption, anonymization, and audit trails

CONCLUSIONS

These findings demonstrate the robustness of the NIS' research quality to develop real world evidence (RWE) suitable for the NIS' objectives. Generating reliable RWE based on robust RWD is crucial for informing future healthcare strategies and regulatory decision making.

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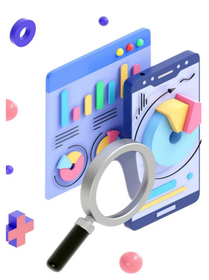
❖ Unique and General Approaches to Data Protection, Integrity, and Quality in this study

Data Protection

- **Vulnerable Population Safeguards**
- **Ethical Consent Process**
- **Confidential Data Handling**
- Encryption Security
- Data Anonymization
- Access Control Measures

- **Surveys completed by parent(s)/guardian(s) for infants and children ≤5 years.**
- **ICF signed by representative, not patient**
- **Secure management of EMR and survey data**

- AES-256 encryption for electronic data
- Patient identifiers anonymized
- Role-based access control
- Secure data storage and restricted access
- Database security managed via Electronic Data Capture (EDC) system



Data Integrity

- **Dual Data Source Collection**
- **Cross-Validation Design**
- **Expanded Risk Factor Identification**
- Standardized Data Entry
- Audit Trails for Data Changes
- Source Data Validation (SDV)
- Discrepancy Management

- **Advanced CRF development enables systematic collection of key variables from both EMR and caregiver surveys**
- **CRF structure allows cross-validation of similar variables (e.g., body temperature & fever, preterm birth status) between EMR and survey data.**
- **Dual data source strategy (chart-review & survey) identifies risk factors not available in medical records**

- Standardized eCRFs for data entry
- Built-in validation rules and audit trails
- Regular data monitoring
- Automated/manual queries for missing/outlier data
- Source Data Validation (SDV) of EMR.

Data Quality Assurance

- **Comprehensive RWD**
- **Inclusive Data Collection**
- **Systematic Data Validation**
- Completeness and Consistency Check
- SDV and Query Resolution
- Internal Audits and Protocol Adherence
- Medical Coding Validation

- **Caregiver surveys broaden RWD collection, capturing social and environmental factors often missing from EMR**
- **Inclusion of both patient and caregiver perspectives enables more comprehensive data**
- **Cross-checking EMR and survey data ensures robust validation and high completeness**

- Completeness checks and missing data analysis
- Internal audits and periodic QC
- Systematic review of query logs
- Medical coding using MedDRA
- Built-in validation rules and audit trails