FRAMEWORK FOR COLLECTING REAL-WORLD DATA WITHIN A PATIENT SUPPORT PROGRAM
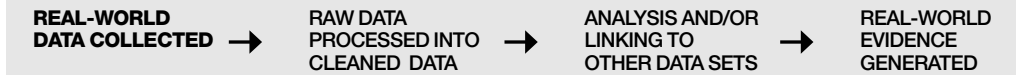
DATA STAGES: FROM REAL-WORLD DATA TO REAL-WORLD EVIDENCE

REAL-WORLD DATA COLLECTED → RAW DATA PROCESSED INTO CLEANED DATA → ANALYSIS AND/OR LINKING TO OTHER DATA SETS → REAL-WORLD EVIDENCE GENERATED

1. PLAN

INCLUDE DATA COLLECTION DURING EARLY PSP PLANNING AND DESIGN

Key elements:

- Define data collection objectives
- Assemble cross-functional team including PSP, Medical, RWE, Access, Marketing, and Legal
- Follow the patient journey to determine data to collect, including data source and frequency
- Ensure appropriate consent is in place

DISCUSSION QUESTIONS FOR CONSIDERATION WHEN DEFINING DATA OBJECTIVES:

- What unanswered questions about the therapy do internal and external stakeholders have?
- Can local population utilization (i.e., patient demographics, patient demand, efficacy, subpopulation stratification) be demonstrated?
- Can adherence be tracked to enable the identification of additional patient needs?
- Are quality of life measurements missing from current data sets?

2. BUILD

BUILD THE DATA COLLECTION PROCESS LEVERAGING THE PSP INFRASTRUCTURE

People, processes, and systems:

- PSP coordinators
- Reimbursement specialists
- PSP nurses
- PSP pharmacists
- PSP specialty pharmacies
- CRM / Patient registries
- IT / Systems
- Pharmacovigilance
- Reporting
- Infusion clinics
- Wholesalers

Data governance and quality:

- Data dictionaries
- Pre-defined protocols
- Training for front-line PSP staff
- Process controls and system-level controls
- Regular monitoring through audits and utilization of the data (i.e., generating and analyzing reports)
- Deviation management
- Defined data roles, including who has visibility to data

ELEMENTS OF THE PSP INFRASTRUCTURE CAN BE IN-HOUSE AT THE MANUFACTURER, SITUATED WITH THE PSP SERVICE PROVIDER, OR BOTH, DEPENDING ON PROGRAM SET UP.

3. COLLECT

COLLECT THE DATA FROM SELECTED SOURCES USING DATA COLLECTION TOOLS

Data sources:

- Physicians
- Nurses
- Patients
- Pharmacists
- Pharmacy systems
- Clinics

PSP data collection tools:

- Baseline data: PSP enrolment form and follow-up enrolment calls
- Adherence calls
- Post-infusion reports
- Post-injection reports
- Clinical observation reports
- Questionnaires
- Interviews
- Patient apps

EXAMPLES OF DATA COLLECTED BY PSP:

- Patient demographics
- Prior therapies
- Therapy start, stop and duration
- Dosing changes
- Stop reason
- Reimbursement data
- Lab tests
- Scans
- Clinical scales
- Patient reported outcome measures (PROMS)
- Quality of Life measures (QOL)
- Overall Survival (OS)