Real-world data for decision-making on therapeutic approaches and health policies: Examples from Greece and Europe

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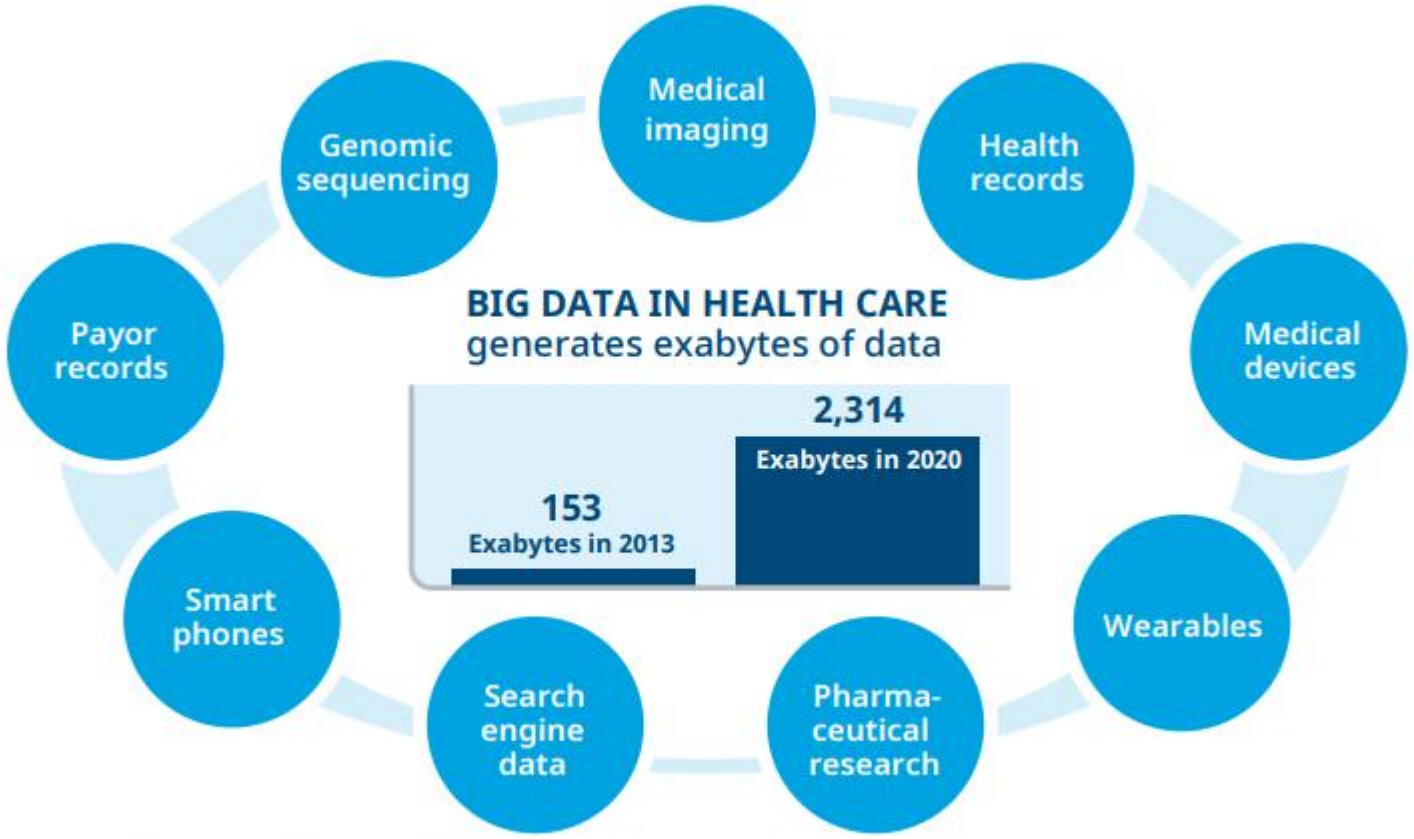
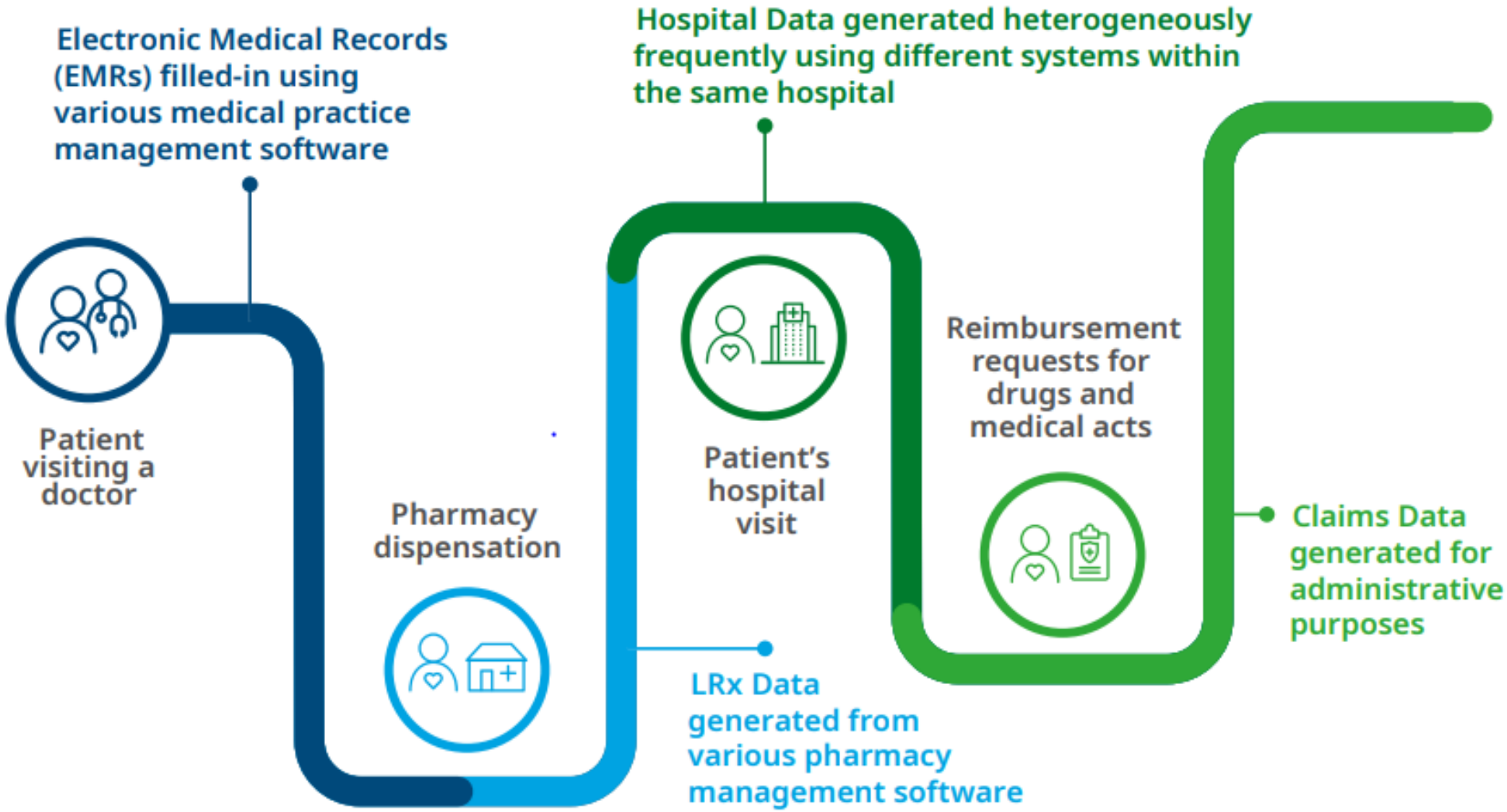
Real World Data sources



Source: "Harnessing the power of data in health".

Data is generated for administrative-patient management purposes, not for analytical-scientific ones



Real World Data challenges

Find

Need for:

- Assets profiled as per a Data Quality Framework
- dynamically updated / orchestrated syndicated catalog
- Robust processes to select fit for purpose data
- Data orchestration capabilities

Interoperate

Enable data sources comparability and interchange with clear understanding of applied data transformation and dissemination processes

Access

Facilitate data access accross multiple settings in a transparent and compliant manner

Reuse

After initial collection, reuse data in a compliant/transparent fashion via all statistical/data science to produce better outcomes

Real World Data possible uses

Clinical Trial Optimization

Identify best sites and most appropriate patients. Support protocol design

- Protocol Design & Feasibility
- On-going protocol adjustment
- Leverage RWD for study comparative arm
- Optimise country allocation
- Site & patient selection

Epidemiology Assessment

Monitoring of pathology evolution and therapeutic strategies

- Understand the natural history of disease
- Characterize patient populations & identify subgroups of interest
- Treatment pathway
- Determine the standard of care
- Identify unmet needs
- Identify suitable local comparators
- Patient flow analysis/ patient journey
- Adherence studies
- Off-label use

Drug Safety & Risk Management

Segment, analyze and assess the safety and risk/benefit of therapeutic interventions in a real-world setting

- Signal detection and assessment
- Safety Surveillance
- Vigilance
- Risk Assessment
- DUS (Drug Utilization Study)
- PASS (Post Authorization Safety Study)

HEOR/ Market Access

Demonstrate the value of medicine through evidence-based health economic evaluation and real-world outcomes for optimal pricing, reimbursement and coverage potential

- Cost of Illness/HCRU (Health Care Resource Utilization)
- Burden of Disease
- Budget Impact
- Outcomes studies
- Comparative Effectiveness
- Compliance & Persistence
- Contract Optimization
- Target population

Commercial Analytics

Diagnose, plan,forecast and track brand performance. Size and characterize the target market from the disease and treatment pattern perspective

- Brand/launch Planning & Strategy
- Market sizing and forecasting
- Brand Diagnostics
- Brand Performance tracking/Source of business
- Split by indication
- Contract Compliance

Real World Data: Navigate a crucial, complex ecosystem to generate insight

Structured & unstructured data

EMR, claims, clinical notes, lab results, pathology reports, clinical trial, omics & safety data, connected devices, scientific literature, social media & more

Text documents, PDFs, FHIR, HL7, CCDA & more

IQVIA Health Data Transformation Platform

Transforms disparate, heterogenous sources into analytical ready data

- **Data integration and master ID management**
- **Natural Language Processing (NLP)**
- **Extensive multi-country specific ontologies out of the box**
- **Leading open data exchange standards (OMOP, FHIR)**
- **Statistical anonymization to GDPR and HIPAA standards**

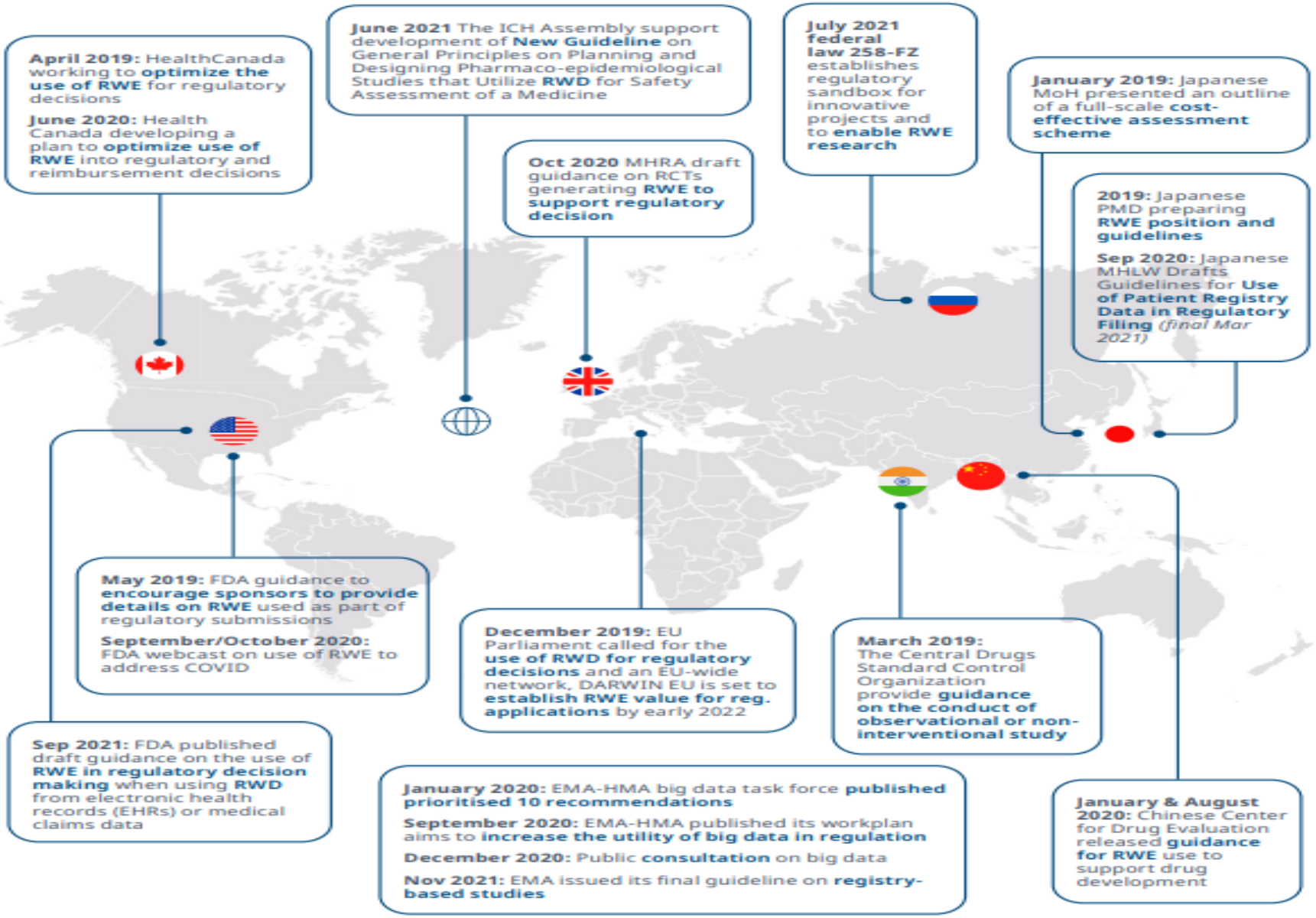
Curated, normalized longitudinal data

Analytics ready, with powerful query and search capabilities

Use cases:

- Manage population health
- Improve quality of care
- Optimize hospital efficiency
- Anonymize highly useful data
- Enhance risk adjustment
- Drive analytics-based insights
- Benchmark health reports

International examples



Examples of RWE throughout the product lifecycle

Increasing role of RWD to potentially generate insights or evidence through-out the product lifecycle

Examples uses in early development

- Evidence planning; Data strategy plan
- External Comparators
- Validate biomarkers and other potential outcomes
- Disease Registries
- Regulatory Intelligence to inform indication and dosage strategy

RWD for RWE post approval

- Demonstrate value & differentiation
- Labeling expansion
- Real-world safety & effectiveness
- Patient perspective/PRO
- Cost-effectiveness
- Implications for Rare Disease (Registry; SOC, Feed Recruitment of Ph2/3

Innovative, RWE solution, analysing longitudinal data for MS & PsO for the first time in Greece

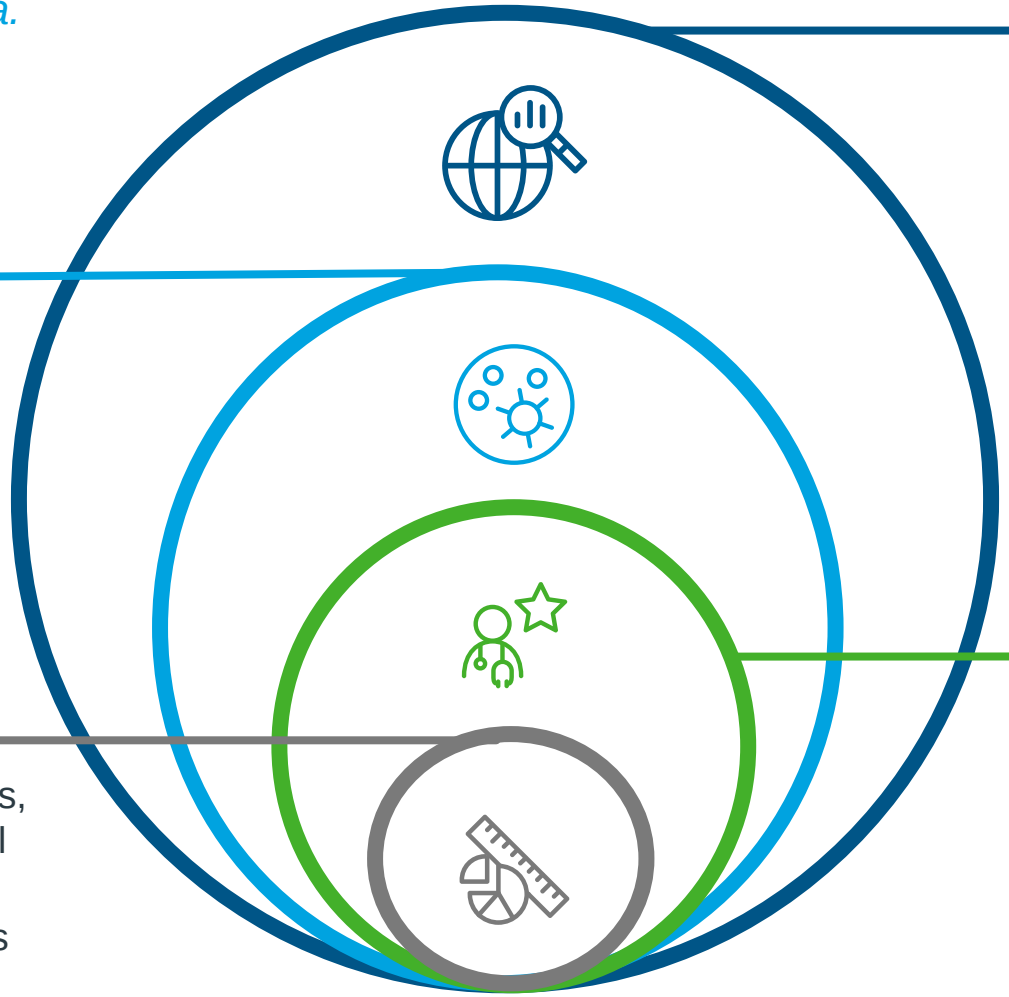
Analysis based on de-identified data.
GDPR compliant. Non-projected.

Diseases

- **Drug-treated** cases of all **neurology diseases**
- No inclusion/exclusion criteria, allowing RWD collection
- Focus on **Neurology** & **Dermatology**

Patient Variables

- **Patient characteristics:** demographics, clinical (commorbities, scales), medical history
- **3 to 5 years'** history of drug treatments



Methodology

Technology based, using 3 EMR data sources:

- **IDIKA e-prescription** platform
- **Medical records**
- **PRO option** embedded

Physician Specialty - customized

LRx (Longitudinal) data

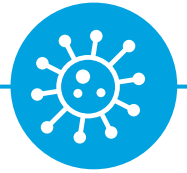
Regular (Monthly) data collection

Patients' companion app

Physicians Specialty

- Neurology hospital **clinics**
- **Private practitioners –** neurologists/ dermatologists

Core features and benefits



- **Stable** panel, **continuous** collection
- **RWD**, not claim nor perception
- **Reliability** for **Medical** claims

Disease

- **~700** active **patients**
- Disease **staging**
- Patient **demographics**
- Patient **profiling**

Patient

- **Insights** and **trends** in disease's **treatment**
- Insights on actual **doctor behavior**
- **Evidence-based** decisions

Treatment

Major variables monitored

Patient & clinical characteristics

Diagnosis, time of first diagnosis, severity level, gender, age, relapse/ progression, smoking status, comorbidities, clinical scores (ex. EDSS)

Drug treatment information

- **Current treatment**: lines of treatment, brand, planned duration, type of treatment (Orals/ Injected)
- Medical **history**: lines of treatment, brand, planned duration, type of treatment (Orals/ Injected), switches

PROs (ad-hoc)

MSIS-29, LMSQoL, Fatigue Severity Scale, FSIQ-RMS etc.

Thank you!