A new direct-to-patient approach to observational clinical research in persons with obesity in Europe

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Motivation

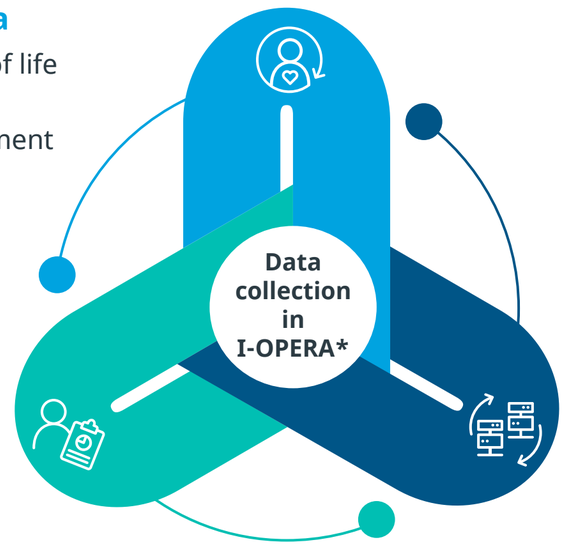
- Both the patient experience and clinical endpoints and variables are important to many observational research objectives in obesity
- In order to collect both patient-reported data and clinical data from health records, many studies typically engage research sites to recruit patients and collect the data. However, there are limitations with this approach, such as limited access to patient populations that may not be connected to traditional research sites, and relevant clinical data may be sitting in multiple care settings
- This study, the IQVIA Obesity Pilot in Europe to test a new patient-centric Research Approach (I-OPERA), aims to test a new research methodology in order to address these challenges

Patient reported data

- Health-related quality of life
- Out-of-pocket and over-the-counter treatment
- Diet and lifestyle
- Social determinants of health

Clinical data

- Treatments and interventions
- Comorbidities
- Healthcare resource use
- Biomarkers



*Not exhaustive

Operational data

- Health record retrieval success rates
- Time to health record retrieval
- Data quality and completeness

Methodology

- The General Data Protection Regulation (GDPR) in the EU and UK GDPR give individuals the right to access a copy of their health data and have that data transmitted to other data controllers. That means that patients have the right to contribute their health data for research if they choose
- This study is testing a direct-to-patient real world data collection methodology based on individuals' rights of data access and portability
- This pilot study will start in England, France and Germany and include adult patients with body mass index ≥ 27kg/m^2
- After receiving approval from ethics committees, patients will be recruited digitally and referred to a direct-to-patient study platform, IQVIA Health Research Space (HRS), where they will complete remote electronic Consent, sign a Data Subject Access Request authorization form and provide details on their healthcare providers
- Virtual site staff will request Electronic Health Records (EHRs) from patients' healthcare providers and abstract relevant clinical information into an electronic case report form; patients will complete a set of surveys including questions related to their quality of life, social determinants of health, lifestyle variables and other information relevant to obesity research
- There will be three central principal investigators (one in each of England, France and Germany) overseeing the study
- If approved by ethics committees, patients will receive a small stipend for participating

Participant recruitment

- Patient Advocacy Groups (PAGs)
- Healthcare provider (HCP) referrals
- Patient panels

Provider contact information

Participants provide contact information for their health care providers in online platform

Patient reported outcomes

Participants complete 30 min online survey, including two validated quality of life instruments

Analysis and reporting

Determine approach viability for future studies, differences between countries, concordance between EHR and patient reported data

Participant enrollment

Self-enrollment via online platform, including
- Remote eConsent
- Data Subject Access Request (DSAR) authorization

Mediate medical record access

HCPs share participant medical records with IQVIA or participant uploads their records to the online platform

Chart abstraction

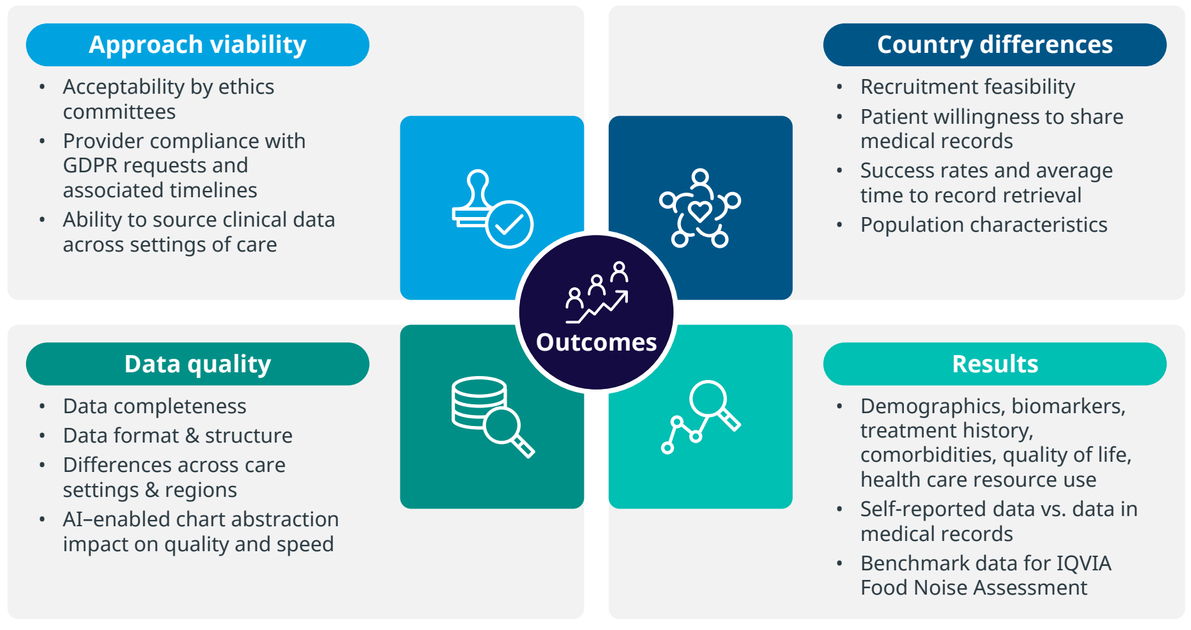
IQVIA Virtual Site abstracts information from health records into electronic case report form

Return of study results

Participants receive email with lay summary of aggregate study results

Impact

- With this study, the aim is to demonstrate that clinical data from EHRs across multiple care settings, together with patient-reported data, can be collected using a fully direct-to-patient study design in Europe
- This pilot study will confirm whether the approach will be accepted by ethics committees, and it will collect operational data on medical record retrieval success rates, average time to record retrieval and information on data quality, format and structure
- If successful, this approach will allow for larger studies to be conducted at lower cost and enable real world studies with primary data collection to more easily include patients who are not connected to traditional research sites



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