

# APEX COPD, USA Primary Care Registry to change COPD outcomes

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## Introduction

- There continue to be treatment gaps in community management of COPD. While continuing medical education can help reduce these gaps, changing patient behavior is key for improvement<sup>1</sup>, and this happens best when patients are involved in their own care.
- APEX COPD (Advancing the Patient Experience in COPD) aims to improve primary care for COPD patients by bringing together electronic medical records (EMR) with Patient Reported Information & Outcomes and presenting this to clinicians and patients in a structured and clinically relevant format at the point of care.
- This will be achieved using modern technology, including Fast Healthcare Interoperability Resource (FHIR), electronic patient surveys, and standardized data collection, and will be guided by a network of COPD clinicians in primary and specialist care.

## Methods

### Operational Model

Delivery of the registry will occur in partnership with the DARTNet Institute (Colorado, USA) and will include 5 essential elements:

- 1.Primary care network:** A network of engaged Primary Care Clinicians and their COPD patients.
- 2.EMR:** Standardized recording of core data using the healthcare record data exchange standard FHIR, to be extended/improved over the course of the registry.
- 3.Patient Reported Information & Outcomes:** Information collected via patient survey, guiding point of care consultations using the Patient Engaged Electronic Reporting System (PEERS).
- 4.Research Database:** Integrated EMR and Patient Reported Information & Outcomes data facilitating data-driven improvements to COPD patient care.
- 5.Clinical Decision Support System (CDSS):** Evidence based Clinical Decision Support (CDS) guiding clinical care & data collection using the Apervita CDS platform will be developed as a limited exploratory aspect of the initiative to be

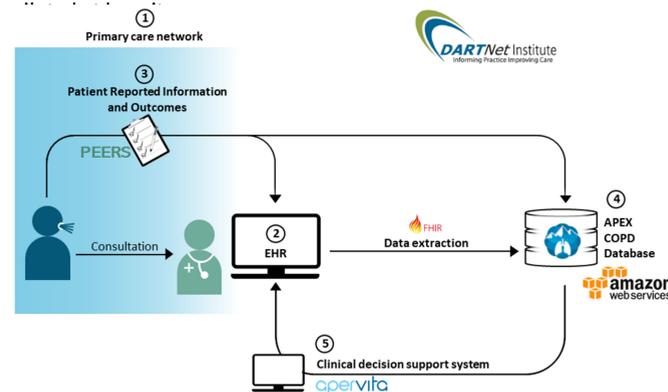


Figure 1 | APEX COPD operational overview.

### Patient Population

APEX COPD will collect EMR and Patient Reported Information & Outcomes data from 3,000+ COPD patients across the USA over a 4-year period (2019-2022).

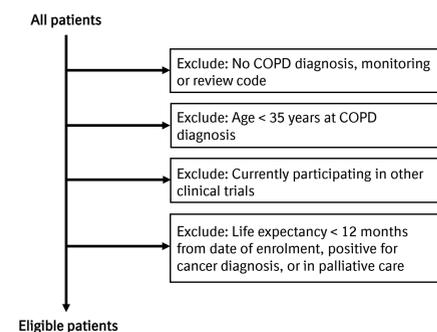


Figure 2 | Patient eligibility for inclusion in the APEX COPD registry.

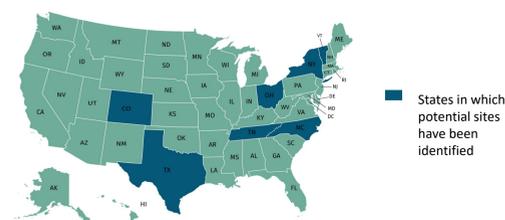


Figure 3 | Patients will be engaged from a number of different sites around the US. Potential sites have been identified in Colorado, Texas, North Carolina, Tennessee, Vermont, New York and Ohio. Sites range from large Safety Net Integrated Delivery Systems, to smaller private clinics. Efforts will be focused on sites with well known EMR systems such as Epic, Cerner and Athena.

### Data collection

A panel of 14 COPD experts in primary and specialist care from the US and internationally have come together to define which data are clinically relevant to collect into the registry from EMR, by Patient Reported Information & Outcomes, and at consultation. This process is being completed using a Delphi method; a process of iterative and anonymous voting which assumes that a group decision is more valid than a decision made by an individual<sup>2</sup>.

Variables under consideration include:

- **Patient demographics.**
- **Medical history and symptoms** (COPD relevant) including prior exacerbations, environmental risk factor exposure, and comorbidities etc.
- **COPD treatment and management** including medications and side effects (such as those related to steroid exposure and/or biologics), adherence data, where available, vaccinations, referrals, surgery, rehabilitation and other non-pharmacological strategies.
- **Patient-reported information and outcomes** including health status scores (CAT, mMRC), and device satisfaction.
- **Medical test/investigations** including spirometry, electrocardiogram, and biomarkers (blood eosinophils, IgE, and FeNO where possible).

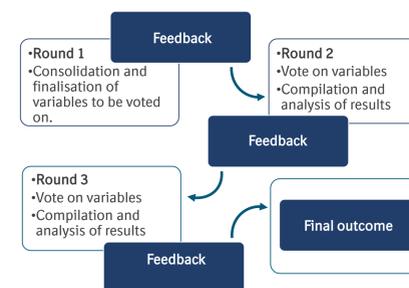


Figure 4 | The Delphi method will constitute of 3 rounds of voting. At the conclusion of each round an independent moderator will summarise the results and present them to all panel members prior to the next round of voting. The final round of voting will bring the panel to a consensus on a group of variables to be collected into the APEX COPD registry. An final decision will be made on the inclusion of any variables which do not reach a consensus by the end of round 3 by the APEX Operational Management Group.

## Results

A panel of 14 COPD experts in primary and specialist care voted on 189 clinical COPD variables for collection into the APEX COPD registry. These variables comprehensively covered EMR and Patient Reported Information & Outcomes data collected for COPD. Variables were collated from current COPD guidelines and recommendations including GOLD guidelines, the American Thoracic Society and the European Respiratory Society.

In voting round 1, 6 variables were added bringing the total to 195. After voting round 2, 5 of the 195 variables were excluded from collection into the registry, 170 were confirmed for collection, and 20 require further voting to reach consensus. Of the 170 confirmed variables it was recommended that 115 be collected from EMR, and 16 via Patient Reported Information & Outcomes (Patient Reporting). Zero variables were confirmed for collection by clinicians at consultation. Data sources were not fully agreed on for a number of variables.

A final round of voting (round 3) was undertaken to vote on variables where consensus was not reached for collection via Patient Reporting and during Consultation. In this round 13 variables were voted to be collected by Patient Reporting, and 2 were voted to be collected at Consultation, these variables were included in the final list to be collected into the registry. Of the remaining undecided variables 4 were confirmed for collection by Patient Reporting, and 3 were confirmed for collection at Consultation by the APEX Operational Management Group (a sub-committee of steering committee members guiding operational direction of the initiative).

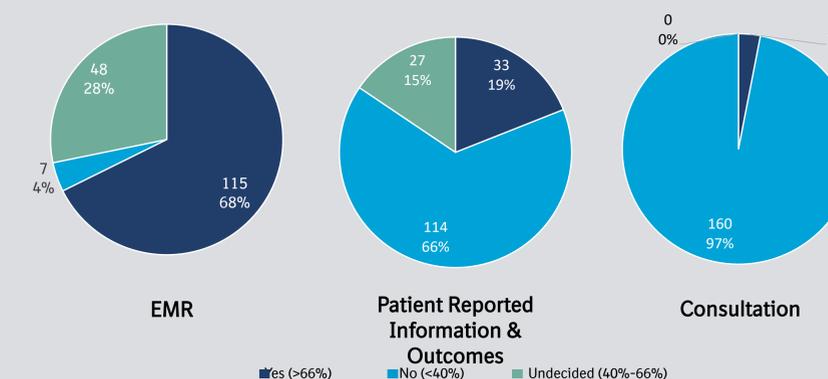


Figure 5 | Overall results from Delphi voting process for variables to be collected from EMR, via Patient Reported Information & Outcomes, or during consultation.

## Conclusions

- Making the patient a valuable player in the decision making behind their treatment i.e. including them in data collection and feedback, will empower patients to improve the outcomes of their condition, and enable clinicians to provide more informed care for their patients.
- The collective data will form a comprehensive repository in the APEX COPD database for research identifying and solving key challenges facing primary care clinicians and their patients with COPD.

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## Acknowledgements

Dr Carlos Tafur provided expert advice during variable selection process. Funding for this initiative is provided by Optimum Patient Care Global (OPCG) and Boehringer Ingelheim Pharmaceuticals, Inc. (BIP). The authors meet criteria for authorship as recommended by the International Committee of Medical Journal Editors (ICMJE). The authors received no direct compensation related to the development of the manuscript. Optimum Patient Care Global (OPCG) and Boehringer Ingelheim Pharmaceuticals, Inc. (BIP) were given the opportunity to review the manuscript for medical and scientific accuracy as well as intellectual property considerations.

