COPD FOUNDATION

BRIDGE Patient to Investigator Training Module 4
Designing, Doing and Sharing a Research Study Summary Document

Phases of Research: Generally, all research studies have different phases, which can be divided into 3 categories:

- **Before: Designing and Planning**
- **During: Doing the Research**
- **After: Sharing the Research**

Before: Designing and Planning:

How to evaluate a research question? A useful way to decide if a proposed research project will provide new evidence related to a decision that is important to patients and caregivers is to break the research question down into four major categories- the **PICO Approach**

P: The **population** of patients/research participants and relevant subgroups of patients
I: The **intervention(s)** relevant to patients in the target population
C: The **comparator(s)** relevant to patients in the target population
O: The **outcomes** that are meaningful to patients in the target population

Patient and caregiver contribution:

- **Identify a problem**: What frustrates, confuses or worries you in your daily life living with COPD?
- **Plan a Study**: Are researchers considering all concerns a patient may have, do you agree with recruitment plan, are study materials clear?
- **Secure Funding**: Write letters of support, invite others to provide support and suggestions.
- **Get Permission**: Review all materials for participants, review informed consent, review plans to share study results.

During: Doing the Research:

Recruitment:

- **Exclusion Criteria Decisions**: based on what specific **issues a participant could have that might confuse the results** or make it unclear if the actual research topic was answered clearly. ***Example:*** patients on oxygen and patients with other health concerns may be excluded because these unique concerns may affect how the participant completes the study.

- **Inclusion Criteria Decisions**: based on the basic traits or behavior a **participant must have to make the research question answerable**. ***Example:*** Must have been diagnosed with COPD, must be at least 45 years old, etc.

Consent:

- Tell participants the potential benefits in clear language without promising too much *and* the potential risks of participating in the research plan in language that is clear but not frightening *and* the rights of the patient in understandable, clear terms. Some studies may not require written consent.

Patient and caregiver contribution:

- **Recruit**: Share what would convince you to join, help identify potential problems which might stop someone from joining a study. Do all the recruitment efforts make sense to you? Do you think other patients will respond to these efforts—based on your own experiences?
- **Consent:** Provide feedback, does it make sense to *you*? Is it written in a way that will be understandable to most patients and/or their families?
- **Collect Information**: Is the burden for the participant reasonable. Are the materials in enough different languages? Is there enough reimbursement for time required?
- **Conduct Analysis**: You will NOT be expected to understand the statistics involved in this step. Members of your team who are statistics experts will complete this step of the project, don't hesitate to ask for the statistical conclusions to be provided to you in simple, plain language.

Collect Information:

- Data (information) can be collected from **surveys,** by reviewing **medical records,** by **interviewing** participants, by **collecting samples or measurements.**

Conduct Analysis (during and after): During and after the study, the research team must **review, organize and attempt to understand** all of the information gathered. **Two types of information (data) may be collected and analyzed*:***

- **Quantitative—**can be measured and given a numeric value and shown in tables and graphs. ***Example:*** *Measure patients' lung function before and after taking a new medicine. Chart these measurements showing change over time.*

- **Qualitative—**based on opinions, preferences, observations, "narratives"—what is told or said via interviews or open-ended questions. ***Example:*** *Interview patients about their experiences/observations while receiving the new medicine. Did patients have similar tales?*

After the Study:

Evaluate Impact:

- **Review the data collected -** when it is available, summarize the data, draw conclusions from the data, answer "Why did we get these results and what do they mean for people enrolled?" Determine how well the research plan answered the original question and what next steps might be.
- **Share Results**:
  Write and publish a medical journal article, present at a scientific/medical conference, share via the internet/website, develop plain language summaries, identify places and methods to share the results and implications.

Patient and caregiver contribution:

- **Evaluate Impact:** Using your experiences as a patient/caregiver, answer questions about collected data. Do you understand why the patients reacted/responded the way they did? Can you share this with the team?
- **Share Results:** Review summaries to make sure they are clear and use simple language, share the study and what you and your team learned with other patients in your support group, in your social network, at a patient-focused conference, etc.