**BRIDGE Patient to Investigator Training  Key Lessons and Highlights**

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| **Module 1: What it Means to be a Patient/Caregiver Investigator** | Patient/caregiver investigators are part of the research team from the beginning through all the phases of the research study. | Patient/caregiver investigators are different from:  
  - research advocates  
  - patient advisors |
| **Module 2: Building Confidence** | • Your perspective is important, unique and needed.  
• Don’t be afraid to speak up.  
• You are teaching your fellow research team members as much as they are teaching you! | To any research team, you bring:  
  - experiential knowledge,  
  - a unique perspective,  
  - curiosity and  
  - the ability to “fill in the gaps” to a research team  

There are several questions you can ask before joining a research team, that will help you understand expectations |
| **Module 3: Types of Research** | • Different types of studies are used to answer different types of questions.  
• Research studies can often be separated into Observational vs. Experimental Studies.  
• Research studies can also be separated into either Quantitative, Qualitative or Mixed Methods studies.  
• Patient-Centered Outcomes Research asks questions and studies topics that are of most interest to patients and their caregivers. | Observational Studies: Observe, measure, record, analyze—no changes  
Experimental Studies: Change, observe the effects of the change, compare, conclude—some type of change/intervention is done  
Quantitative studies: Data gathered and analyzed as numbers  
Qualitative studies: Information collected is often ideas, opinion, beliefs, attitudes, concerns (ideas)  
Mixed Methods: uses both quantitative and qualitative data/analysis |
### Module 4: Designing, Doing and Sharing a Research Study

**Before a study:** Identify a problem, plan a study, secure funding, get permission

**During a study:** Recruit and consent participants, collect information, conduct analysis

**After a study:** Evaluate impact, share results

During ALL phases of a study, there is an important needed role for patient/caregiver investigators

Generally, research studies can be divided into different phases/stages:
- Designing and planning *(before study)*
- Doing the research *(during study)*
- Sharing the research *(after study)*

### Module 5: Specific COPD-Related Research Information

Past and current research studies on COPD have focused on all aspects of COPD—from understanding it at the molecular/cellular level to diagnosing criteria to treatment to understanding its causes and risk factors.

Future COPD research will likely focus on more understanding of all of these issues along with:
- better understanding whether COPD affects women differently;
- expanding current criteria for diagnosing COPD; and
- finding new treatments and ultimately, hopefully, a cure

Research studies on COPD have focused on:
- Defining COPD
- COPD at the Molecular/Cellular level
- Trajectory of COPD (what happens over time)
- COPD epidemiology (patterns, frequency, causes, risk factors)
- Oxygen Issues and Therapies
- Asthma and COPD (the “overlap”)
- COPD Phenotypes (types, common traits)
- Screening for COPD (identifying undiagnosed)
- Non-smoking Risk Factors
- COPD Hospital Readmission Issues

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## Module 6: Key Types of Study Documents

As an active member of the research team you will be asked to review all of these different types of documents.

Your feedback on these documents is important to help ensure the patient/caregiver point of view is considered.

Most research studies will have these key documents:
- A research proposal
- A study protocol
- A statistical analysis plan
- An informed consent document
- Patient-facing documents

These documents provide, respectively, a summary of the study, key details and step-by-step study plans, how the data will be analyzed, risks/benefits of the study and the many materials used directly with the study’s participants.

## Module 7: Protections for Research Participants

Strong protections and federal regulations for people participating in research are in place today to avoid repeating past abuses.

These protections include:
- Institutional review boards
- Informed consent
- Extensive privacy and confidentiality protections through the Health Insurance Portability and Accountability Act (HIPAA)

Today’s research protections developed overtime because of these historical moments:
- Nazi experimentation (early 1940s)
- Nuremberg “trial” and “Code” (1946-47)
- Willowbrook Home for Children study (1963-1966)
- Declaration of Helsinki (1964)
- Tuskegee Syphilis study (1932-1972)
- National Research Act (1974)
- Belmont Report (1979)