CLINICAL TRIAL RESOURCES

FOR ADVICE & INFORMATION — **Your treating physician and/or clinical investigator**

FOR ADDITIONAL INFORMATION — **IFOPA**
ifopa.org/clinical_trials

FOR GUIDELINES — **National Institute of Health**
clinicaltrials.gov

U.S. Food & Drug Administration
fda.gov/ForPatients/ClinicalTrials

European Medicines Agency
clinicaltrialsregister.eu

CONSIDERATIONS FOR CLINICAL TRIAL PARTICIPATION

» Potential safety and effectiveness of the medication
» Sponsorship and conduct of the trial
» Access to treatment during the trial, after the trial (e.g. extension trials)
» Route of administration
» Dosing frequency
» Travel to sites/time commitment
» Additional study procedures
» Trial costs
» Plans to publish the results

QUESTIONS PARTICIPANTS CAN AND SHOULD ASK

SOME QUESTIONS YOU MIGHT ASK ABOUT THE RESEARCH INCLUDE:

» What is the purpose of the study?
» Who is sponsoring the study?
» Who has reviewed and approved this study?
» Why does the research team think the treatment/drug will work?

SOME QUESTIONS ABOUT YOUR PARTICIPATION IN THE STUDY INCLUDE:

» Where is the study site?
» What kinds of therapies, procedures, and/or tests will I have during the trial?
» Will they hurt? If so, for how long?
» How long will the study last?
» How often will I have to go to the study site?
» Who will provide my medical care after the study ends?
» Will I be able to take my regular medications during the trial? Do I need to avoid any medications?
» What medications, procedures, or treatments must I avoid while in the study?
» Will I have to be in the hospital during the study?
» Will I be able to find out the results of the trial?
» Will I have to pay anything to participate in the study?

SOME QUESTIONS ABOUT RISKS INCLUDE:

» What is known about the potential adverse effects of the treatment?
» What are the possible immediate and long-term side effects?