Defining the Terms

PREP (Preparing for Roles as Expert Patients)

Research, Advocacy, and Healthcare: Acronyms and Terms

While this list does not include every acronym or term you may come across, it should cover most of the terms encountered in the PREP training courses. If you think we’ve missed an acronym or term that you find important, please email AFScience@arthritis.org with the acronym and its definition and we’ll consider it for the next version.

**AAOS – American Academy of Orthopaedic Surgeons.** This group engages in health policy and advocacy activities on behalf of patients with arthritis and joint or bone injuries, and doctors who perform orthopedic surgery. They provide continuing education for orthopedic surgeons and others worldwide.

**ACR - American College of Rheumatology.** A global non-for-profit medical society of doctors, other health professionals, students, and scientists whose goal is to improve the care of patients with rheumatic disease.

**Arthritis Foundation -** Founded in 1948, the Arthritis Foundation is focused on finding a cure and championing the fight against arthritis with life-changing information, advocacy, science and community.

**Blinded/Masked Study** – The subject, investigator, or both do not know which intervention (test or placebo) is being used in a study.

**CARRA - Childhood Arthritis and Rheumatology Research Alliance.** Its main goal is to support collaborative research to prevent, treat and cure pediatric rheumatic diseases. Every pediatric rheumatologist in North America is a member of CARRA. CARRA’s vision is to have every patient participate in research in some way. PARTNERS helps bring this vision to reality.

**CER - Comparative Effectiveness Research.** - Research that involves a direct comparison of current health care interventions to determine which works best for patients, and under what circumstances. CER looks at which treatments, preventions, or diagnostics offer the greatest benefits and harms.

**ClinTrials.gov -** A worldwide database registry of clinical studies that use human research subjects.

**Crossover study** - A study where each subject gets both interventions (test or placebo) at different times during a study.

**CTTI - Clinical Trials Transformation Initiative.** A group of over 80 organizations whose goal is to develop and drive practices that increase the quality and efficiency of clinical studies.
**DMARDs** - Disease-modifying anti-rheumatic drugs that include things like:

- methotrexate
- hydroxychloroquine (*Plaquenil*)
- sulfasalazine (*Azulfidine*)
- leflunomide (*Arava*)

**DSMB/DMC - Data Safety and Monitoring Board/Data Monitoring Committee.** A group of experts (not directly involved in a study) who review study data at various time points to protect the safety and welfare of subjects taking part in the study.

- A DSMB or DMC is often required for multi-site studies that use interventions with higher potential risk to the subject.
- Based on the review of data, a DSMB or DMC may recommend that a study be continued, modified, or stopped.
- Increasingly, patients are beginning to serve on DSMBs and DMCs.

**EHR - Electronic Health Record.** An electronic version of a patient’s medical history, that is maintained by the provider over time, such as past medical history and medications.

**FAERS - Federal Adverse Event Reporting System.** The federal safety surveillance system database that contains information on adverse events (things like bad reactions or safety issues) and drug error reports sent to the FDA as part of the safety program for all approved drug and therapeutic biologic products.

- It contains adverse drug reaction reports submitted to the FDA by manufacturers as required by regulations.

**HIPAA - Health Insurance Portability and Accountability Act.** Passed in 2003, HIPAA is a law that protects privacy and patient medical records. HIPAA allows patients to control how their health facts are used and shared.

**Title I of HIPAA**
- protects health insurance coverage for workers and their families when they change or lose their jobs.

**Title II of HIPAA, known as the Administrative Simplification (AS) provisions**
- requires the establishment of national standards for electronic health care transactions and
- national identifiers for providers, health insurance plans, and employers.
HHS (or DHHS) - *U.S. Department of Health and Human Services*. The US government agency that works to enhance and protect the health and well-being of Americans. HHS has **11 divisions**

- 8 in the US Public Health Services (PHS)
- 3 human services agencies

**PHS - US Public Health Services.** The 8 divisions of HHS that deliver public health promotion and disease prevention programs, as well as advance public health science.

- **AHRQ - Agency for Healthcare Research and Quality.** Its main goal is to collect and use evidence to make health care safer, higher quality, more accessible, fair and affordable.

- **ATSDR - Agency for Toxic Substances and Disease Registry.** Focuses on minimizing health risks associated with human exposure to hazardous substances.

- **CDC - Centers for Disease Control and Prevention.** The leading public health institute in the US. Its main goal is to protect public health and safety by finding ways to prevent and control
  - disease
  - injury
  - disability

- **FDA - U.S. Food and Drug Administration.** Protects and promotes public health through the control and supervision of:
  - food safety
  - tobacco products
  - dietary supplements
  - prescription and over-the-counter drugs
  - vaccines
  - biologic medical products
  - blood transfusions
  - medical devices
  - electromagnetic radiation emitting devices (ERED)
  - cosmetics
  - animal foods & feed
  - veterinary drugs and products.
• **HRSA - Health Resources and Services Administration.** Works to improve health and health equity through access to quality services, a skilled health workforce and innovative programs. HRSA’s programs provide health care to people who are
  o geographically isolated,
  o economically vulnerable, or
  o medically vulnerable.

• **IHS - Indian Health Service.** Principal federal health care provider and advocate for about 1.9 million American Indians and Alaska Natives who belong to 567 federally recognized tribes.

• **NIH – National Institutes of Health.** Primary US government agency responsible for biomedical and health-related research.
  o *Intramural Research Program (IRP)* conducts NIH research in 27 separate institutes and centers.
  o *Extramural Research Program (ERP)* provides major biomedical research funding to non-NIH research facilities.

• **SAMHSA – Substance Abuse and Mental Health Services Administration.** Works to improve the quality and availability of prevention, treatment, and rehabilitative services for substance abuse and mental illnesses.

**Human Services Agencies**

• **ACF – Administration for Children and Families.** This agency works to promote the economic and social well-being of families, children, individuals and communities. It oversees 60 programs that target children, youth, and families. These programs include services for:
  o assistance with welfare
  o child support enforcement
  o adoption assistance
  o foster care
  o child care
  o child abuse
• **ACL – Administration for Community Living.** The goal of this agency is to maximize the independence, well-being, and health across the lifespan for:
  - older adults
  - people with disabilities
  - and offer support and solutions to their families and caregivers.

• **CMS - Centers for Medicare & Medicaid Services.** Administers the Medicare program and works in partnership with state governments to administer:
  - Medicaid
  - the State Children's Health Insurance Program (SCHIP)
  - health insurance portability (HIPAA) standards.

  In addition to these programs, other CMS responsibilities include oversight for:
  - quality standards and the certification process for long-term care facilities (more commonly referred to as nursing homes)
  - clinical laboratory quality standards under the Clinical Laboratory Improvement Amendments (CLIA)
  - HealthCare.gov.

**HRA – Health Research Alliance.** A collaboration of non-for-profit, non-governmental funding groups that support health research and training for biomedical science applications that advance health.

  - The Arthritis Foundation is a member.

**ICF - Informed Consent Form.** This is a form that is signed before joining a research study. The form has details about the study and its potential risks and benefits.
IDE – Investigational Device Exemption. A request made by a device company to the FDA to use a new device in a clinical study to collect required safety and effectiveness data. The data from the clinical study will be used to determine whether the new device may be approved to support one of the following submissions to FDA:

- a premarket approval (PMA), the process the FDA uses to review the safety and effectiveness of a device before it is approved for marketing to the public, or
- a premarket notification (510[k]), a process the FDA uses to evaluate if a device can be marketed without going through premarket approval because it is similar to another FDA-approved device.

IND – Investigational New Drug. A request made by a drug company to the FDA to use a new drug or biological product (“biologic”) in a clinical study to collect required safety and effectiveness data. The data will be used to determine whether the new product may eventually be FDA-approved for marketing to the public.

IRB - Institutional Review Board. This group reviews and approves research on people. The purpose of the IRB is to make sure that all human research is conducted in accordance with all federal, institutional, and ethical rules.

JA – Juvenile Arthritis. Term used to describe the many autoimmune/inflammatory conditions or pediatric rheumatic diseases that can develop in children under the age of 16.

JIA - Juvenile Idiopathic Arthritis. Considered the most common form of JA, this form includes six subtypes:

- Oligoarthritis (affects 2 or 4 joints during the first 6 months of the disease)
- Polyarthritis (affects 5 or more joints at the same time)
- Systemic arthritis (affects the entire body)
- Enthesitis-related arthritis (affects the tissue where tendons or ligaments attach to bone)
- Juvenile psoriatic arthritis (affects both skin and joints)
- Undifferentiated arthritis (does not fit into any of the above categories or fits into more than one type of JIA)
LHS - Learning Healthcare System – A collaborative approach that shares data and insights across boundaries to drive better, more efficient medical practice and patient care. The LHS is linked by shared electronic health records and databases. This interconnected system can be supported by clinical research and data analysis and relies on technology to manage and communicate data that helps guide the decisions made by health systems, care providers, and patients and their families.

MDR – Medical Device Reporting. The federal regulation that outlines requirements for manufacturers, importers, and device user facilities to report device-related adverse events and product problems to the FDA.

NIAMS – National Institute of Arthritis, Musculoskeletal, and Skin Diseases. One of the NIH institutes dedicated to supporting research into the causes, treatment, and prevention of arthritis, musculoskeletal, and skin diseases. This includes

- Training scientists to carry out research for these diseases
- Sharing of information on research progress for these diseases

The NIAMS Coalition is an independent national consortium of professional and voluntary organizations.

- The coalition raises awareness about NIAMS research on the basic understanding, causes, incidence, treatment, and prevention of bone, joint, muscle, and skin diseases.
- As key partners of the NIAMS, they serve as the voices of the patients and professionals affected by NIAMS research.

NHC – National Health Council. A non-profit group that includes more than 100 national health organizations.

- NHC strengthens the work of patient advocacy organizations, develops public awareness and advocacy programs, supports health research, and works to influence the health care reform debate.
- The Arthritis Foundation is a voluntary health agency member.

OA – Osteoarthritis. The most common chronic condition of the joints, involving a breakdown of the cartilage or cushion between joints.
OHRP – Office for Human Research Protections. Provides leadership in the protection of the rights, welfare, and well-being of human subjects involved in research conducted or supported by HHS. For some research not conducted or supported by HHS, OHRP also:

- provides clarification and guidance
- develops educational programs and materials
- maintains regulatory oversight
- provides advice on ethical and regulatory research issues

OAAA – Osteoarthritis Action Alliance. This group is committed to elevating osteoarthritis (OA) as a national health priority and promoting effective policy solutions that address the individual and national toll of OA. The Arthritis Foundation and the Centers for Disease Control and Prevention (CDC) are founding members of this organization.

OARSI – Osteoarthritis Research Society International. OARSI is an international organization for scientists and health care professionals focused on the prevention and treatment of OA through the promotion and presentation of research, education and the worldwide dissemination of new knowledge.

OMERACT – Outcome Measures in Rheumatology. An international network of patients and health professionals interested in outcome measures in patients with musculoskeletal conditions. OMERACT recommendations are based on data and prepared and updated by expert working groups. OMERACT recommendations include core sets of measures for most major rheumatologic conditions.

PARTNERS – Patients, Advocates, and Rheumatology Teams Network for Research and Service. A patient-powered network of researchers, patient communities, clinicians and health care systems.

- It formally links childhood arthritis and lupus patients, family members, the CARRA network, the Lupus Foundation of America, the Arthritis Foundation and a quality improvement network called PR-COIN.
- The group works to improve the lives of children with rheumatic diseases through research that matters to patients.
Patient self-advocacy - is the ability to speak-up for yourself and the things that are important to you and your disease management. Being a self-advocate means:

- you ask for what you need and want and tell people about your thoughts and feelings
- you know your rights and responsibilities. You speak-up for your rights.
- you make choices and decisions that affect your life. The goal of self-advocacy is for YOU to decide what you want then develop and carry out a plan to help you get it.

Self-advocacy does not mean you can’t get help if you need or want it, it just means that you are making the choices and you are responsible for the choices you make.

PCOR – Patient-Centered Outcome Research. Research that addresses the questions and concerns most relevant to patients.

- PCOR includes patients, caregivers, clinicians, and other healthcare stakeholders, along with researchers, throughout the research process.
- PCOR uses comparative clinical effectiveness research (CER).

PCORI – (National) Patient-Centered Outcome Research Institute. An independent nonprofit, nongovernmental group that strives to improve the quality and relevance of evidence to help patients, caregivers, health care professionals, and others involved in the health care system make informed health decisions using data collected from PCOR.

PFDD – Patient-Focused Drug Development. An FDA initiative designed to more systematically obtain patient perspectives on specific diseases and their treatments.

PFDD meetings give FDA an opportunity to listen to patients, patient advocates, and caretakers about:

- the symptoms that matter most to them
- the impact the disease has on patients’ daily lives
- patients’ experiences with currently available treatments.

This can inform FDA’s decisions and oversight during drug development and during review of a drug, biologic, or device marketing application.

Placebo - An inactive drug or “fake” form of therapy given to compare its effects to an active or test treatment.
**PHI – Protected Health Information.** Health information that can be linked to a specific individual as defined by the HIPAA of 1996. It includes

- names,
- geographic identifiers smaller than a state,
- dates (other than year) directly related to a person,
- phone and fax numbers,
- social security numbers,
- medical record numbers and health insurance beneficiary numbers,
- account numbers,
- certificate/license numbers,
- vehicle identifiers,
- email addresses, device identifiers, URLs, and IP addresses,
- biometric identifiers (finger prints, retinal and voice prints), and
- full face photos.

**PPRN – Patient Powered Research Networks.** Research networks that include patients and/or caregivers who play an active role in patient-centered CER.

**PR-COIN – Pediatric Rheumatology Care and Outcomes Improvement Network.** A quality improvement (QI) network of rheumatologists and other health care professionals who work at rheumatology centers and partner with families to transform how care is delivered to children with JIA. PR-COIN is working to:

- develop and evaluate specific disease management strategies to improve JIA care
- create a network that uses a registry database to measure performance, to learn about the health status of JIA patients, and to inform future projects.

**PRO – Patient Reported Outcomes.** Any report of status of a patient’s condition that comes directly from the patient, without external interpretation of the response (i.e., from the healthcare professional, caretaker, or others).

**RA – Rheumatoid Arthritis.** An autoimmune disease in which the body’s immune system mistakenly attacks the joints.

**RAPID-3 – Routine Assessment of Patient Index Data 3.** is a score used to evaluate how severe a disease is based on symptoms like a patient’s function and pain.

**Self-efficacy** - refers to a person’s belief in his or her ability to get to a desired outcome. It reflects confidence in the ability to exert control over your motivation, behavior, and social environment.
SHARP Method - *Sharp van der Heijde Score* – a method for scoring radiographs of hands and feet in patients with RA which is now a reference method used in most clinical and longitudinal observational studies.

The 21st Century Cures Act - The 21st Century Cures Act modified the FDA Drug Approval process to speed up the process by which new drugs and devices are approved.

It eases the requirements put on drug companies looking for FDA approval on new products or new indications on existing drugs by allowing companies to provide "data summaries" and "real world evidence" (RWE) rather than requiring full clinical study results for approval. Examples of RWE include observational studies, insurance claims data, patient input, and anecdotal data. For people with arthritis, this may mean:

- Incorporating patient-focused drug development strategies, allowing the patient’s voice and experience to be considered during new drug development.
- Increasing patient use of health information technology, helping people with arthritis have the most timely and up-to-date health information.
- Increasing support programs that will expand and improve mental health and substance abuse services, helping people with arthritis who also live with mental health and substance abuse disorders.
- Requiring guidance that will help qualify biomarkers and target therapies, greatly benefiting people with osteoarthritis who don’t yet have targeted drug therapies to address their disease.
- Attracting more scientists into the research field.
- Supporting efforts to improve telehealth services in Medicare, helping people with arthritis gain access to physicians they might not otherwise have access to.
- Improving the process for determining which Medicare treatments are covered, leading to increased access to arthritis treatments for Medicare beneficiaries.
- Allowing Medicare beneficiaries to shop for services find the most cost-effective treatments available.

WOMAC - *Western Ontario and McMaster Universities Arthritis Index*. A widely used, set of standardized questionnaires used by health professionals to evaluate the condition of patients with OA of the knee and hip, including pain, stiffness, and physical functioning of the joints.