IDEOM
INTERNATIONAL DERMATOLOGY OUTCOME MEASURES

# PATIENT RESEARCH PARTNER GLOSSARY

This document will provide a list of key terms with definitions that will help you navigate the sessions at the IDEOM meeting.

## Methodology Terms:

**Baseline:** the initial assessment of a study subject performed at the start of a research study before any treatment has been given. Also termed the *week 0* assessment. The effect of an intervention can be determined by comparing scores at *baseline* to *follow up* (see **follow up**).

**Bias:** something that distorts a research outcome or the interpretation of research data.

**Blinded trial:** a study in which research subjects or investigators do not know whether they are receiving the active drug under study or a *placebo* (non-active drug). Essentially, they are *blinded* to whether they are receiving the active drug or the placebo. *Single blind* means only the patient doesn't know whether they get the active drug or placebo. *Double blind* means that neither the patient nor the investigators of the study knows whether the subject is receiving the active drug or *placebo* (see **placebo**).

**Clinically relevant:** a principle, fact, or research study that is directly applicable or important to patient care in a clinical setting.

**Clinical trial:** a large research study that test if a therapy works, if it works better than other available treatments, and if it is safe. Clinical trials involve giving study subjects a treatment that is being study. This is in contrast to an *observational study* in which study subjects are not given treatments but are, instead, observed without any intervention. Clinical trial data is considered a type of evidence (see **evidence** and **observational study**).

**Clinimetrics:** the science of clinical measurement. Psychometrics applied to measures or instruments used in a clinical setting (see **instrument**, **measures**, and **psychometrics**).

**Concurrent validity:** the degree to which instrument scores correlate (exhibit a mutually similar relationship) with scores of a *gold standard* measure at the *same* point in time. This is in contrast to *predictive validity* which assesses the ability of a measure to *predict* the scores of a gold standard instrument at a *future* point in time (see **gold standard**, **criterion validity**, and **predictive validity**).

**Construct:** the *things* or *topics* measured by outcome measures. Examples of constructs include *health-related quality of life*, *disease severity*, and *treatment satisfaction* (see **outcome measures**, **health-related quality of life**, and **treatment satisfaction**).

**Construct validity:** the accuracy in which an instrument measures the *construct* or *thing* it claims to measure. A type of validity. The two types of construct validity are *convergent validity* and *divergent validity*. (see **construct, validity, convergent validity,** and **divergent validity**)

**Content validity:** the extent in which the questions of an instrument (the instrument's *content*) is an adequate reflection of the construct or thing it intends to measure, as judged by *experts*. This is in contrast to face validity, which is judged by *patients* (see **validity** and **face validity**).

**Control group:** the study group in a clinical trial that is given an inactive drug (also known as the *placebo*). Outcomes in the *control group* are compared to outcomes in the *treatment group* (group that received the active drug). This minimizes *bias* by discerning which outcomes are due to the real effect of the treatment versus those that are caused by natural background variation in the way patients feel (see **clinical trial, placebo, outcome, treatment group**, and **bias**).

**Convergent validity:** the degree to which scores of the instrument are positively correlated (exhibit a mutually

similar relationship) with scores of instruments that measure the same *construct* or *thing*. For example, a measures of psoriasis symptoms should be positively correlated with measures of disease severity such that, as measures for psoriasis symptoms worsen (scores increase), so do measures of disease severity. A type of construct validity (see **construct** and **construct validity**).

**Core Outcome Set (COS):** a set of outcomes mandated by experts to be measured in each clinical trial for a specific disease. The outcomes in a specific core outcome set are also referred to as domains, which each measure a specific *construct* or *thing* (see **clinical trial, outcome, domain,** and **construct**).

**Criterion validity:** the ability of an instrument to act like a *gold standard* measure. The two types of criterion validity are *concurrent validity* and *predictive validity* (see **gold standard, concurrent validity,** and **predictive validity**).

**Delphi method:** a group communication process with the aim of achieving agreement on a specific issue among a group of people with very different perspectives and fields of expertise. The Delphi method is utilized when there is little or no published information on the subject under consideration. This process involves several rounds in which questionnaires are sent to experts and patients. The anonymous responses are then collected and shared after each round to inform subsequent rounds. The process is repeated until agreement is reached. Since the process is anonymous, it avoids 'power struggles' and influences of certain individuals in the group. It enables the combination of many opinions into a group response that can be completed in a short time as possible.

**Descriptors:** unique definitions provided for each question choice in an instrument or measure. These definitions describe the features that would constitute selection of that choice. For example, the descriptor for rating a patient as severe in the investigator global assessment instrument for psoriasis reads 'very marked plaque elevation, scaling, and/or erythema;' Descriptors are also referred to as *anchoring language* since it helps *anchor* raters on an idea of what each instrument score and choices for scoring mean (see **instrument** and **measure**).

**Divergent validity:** the degree to which scores of the instrument are negatively correlated (exhibit a mutually opposite relationship) with scores of instruments that measure the opposite *construct* or *thing*. A type of construct validity. For example, an instrument that measures health-related quality of life should be negatively correlated with an instrument that measures disease severity such that measures of health-related quality of life improve (scores increase) with improvements in measures of disease severity (scores decrease) (see **construct** and **construct validity**).

**Domain:** an established unique *outcome* or *construct* that comprise a *Core Outcome Set*. For example, treatment satisfaction is construct that is considered an IDEOM domain and part of the Core Outcome Set for psoriasis clinical trials (see **outcome, construct,** and **Core Outcome Set**).

**Efficacy:** the extent to which a treatment under study improves outcomes in a clinical trial (see **outcome** and **clinical trial**).

**Eligibility criteria:** a pre-defined set of factors that must be met for inclusion (*inclusion criteria*) or exclusion (*exclusion criteria*) in a clinical trial (see **inclusion criteria, exclusion criteria,** and **clinical trial**).

**Evidence:** knowledge gained through scientific research. There are 4 levels of evidence: meta-analyses, clinical trials, observational trials, and expert opinions (see **meta-analysis, clinical trial, observational trial,** and **expert opinion**).

**Evidence-based medicine:** conscientious, explicit, and judicious use of the currently available best *evidence* (from the scientific literature) to make decisions about what is done for patients in clinical practice (see **evidence**).

**Exclusion criteria:** pre-defined factors that exclude a subject from a trial. Part of a study's *eligibility criteria*. For example, many subjects exclude pregnant women or those who are less than 18 years old (see **eligibility criteria**).

**Expert opinion:** opinions of experts in the field, often presented in the form of a published editorial or research letter. Expert opinion is considered a type of evidence (see **evidence**).

**Face validity:** the extent in which the questions of an instrument is an adequate reflection of the *construct* or *thing* it intends to measure, as judged by *patients*. This is in contrast to content validity, which is judged by *experts* (see **validity** and **content validity**).

**Feasibility:** the practicality of an instrument for use in its intendent setting (research study or clinical practice). Elements of feasibility include how easy and time-consuming it is to administer and interpret.

**Follow up:** assessments of a research subject in a clinical trial that follows the baseline assessment. Follow ups occur at certain weeks of the study; for example, week 2 follow up denotes a follow up assessment of the research subject two weeks after the baseline (week 0) assessment. . The effect of an intervention can be determined by comparing scores at *baseline* to *follow up* (see **baseline**).

**Global assessment:** an instrument or measure that asks raters to provide one score on how how a patient is doing overall. Can be reported by patients (patient global assessment) or by a physician or researcher (physician global assessment or investigator global assessment). Patient global is a patient-reported outcome (PRO) and investigator global is a physician-reported outcome. Both are IDEOM domains included in the Core Outcome Set (see **instrument, measure, patient-reported outcome, outcome, domain,** and **Core Outcome Set**).

**Gold standard:** the best outcome measure among all the other outcome measures that exist for measuring a specific construct. Criterion validity measures how scores on a certain instrument positively correlate (exhibit a mutually similar relationship) with scores of the 'gold standard' instrument that measures the same construct (see **construct** and **criterion validity**).

**Health-related quality of life (HRQoL):** the effect of an individual's health on their quality of life (see **quality of life**). HRQoL includes the effects of health on physical, mental, emotional, and social functioning.

**Hypothesis:** a proposed mechanism that might explain a known fact or observation. Hypotheses are tested by a well-designed research study. Unlike theories, hypotheses are asked in the form of questions. For example, does a psoriasis patient on biologic therapy have improved health-related quality of life, as measured by the Dermatology Life Quality Index (DLQI)?

**Inclusion criteria:** pre-defined factors for inclusion a subject for a trial. Part of a study's eligibility criteria. For example, often times, subjects must have a certain disease severity to be included in a clinical trial (see **eligibility criteria**).

**Instrument:** a tool used to measure something; instrument and measure are used interchangeably and mean the same thing (see **measure**).

**Internal consistency:** the degree of inter-relatedness or commonality among questions in a questionnaire or instrument that measure the same construct. A type of reliability (see **instrument, construct,** and **reliability**).

**Intra-rater reliability:** the degree to which instrument scores from the same patient are consistent when measured by the *same person/rater* under the same conditions but at *different time points*. Also called **test-retest reliability**. A type of reliability (see **instrument** and **reliability**).

**Inter-rater reliability:** the degree to which instrument scores from the same patient are consistent when measured under the *same conditions* and at the *same time points*, but by *different people/raters*. Also called **test-retest reliability**. A type of reliability (see **instrument** and **reliability**).

**Investigator:** a researcher conducting and administering assessments in a research study.

**Lesion:** an area of the skin that contains a manifestation of the skin disease. For example, a psoriasis plaque on the knees are considered psoriatic lesions.

**Measure:** a tool used to measure something; instrument and measure are used interchangeably and mean the same thing (see **instrument**).

**Measurement properties:** well-established ways of characterizing the quality of an instrument. These properties include: validity, reliability, and responsiveness (see **validity, reliability,** and **responsiveness**).

**Meta-analysis:** a study that combines information or *data* from published studies and applies statistical methods to that collection of *data* to answer a specific question. Similar to a systematic review in that data from several studies are combined to reach a conclusion. Differs from systematic reviews in that statistical methods are applied to this data to reach this conclusion. Meta-analysis data is considered a type of evidence. (see **evidence** and **systematic reviews**).

**Minimal clinical important difference (MCID):** the smallest change in a measure's score that a patient would identify as important.

**Minimal detectable change (MDC):** the smallest difference in an outcome that can be statistically detected in a given study. Also known as the **smallest detectable change (SDC)**.

**Observational trial:** a type of study that draws conclusions by observing subjects overtime without providing a study treatment (no *treatment group*). While being observed, study subjects can take medications prescribed by their personal doctor, but they are not given any medications by the study team. This is in direct contrast to clinical trials. Observational trial data is considered a type of evidence (see **evidence, treatment group,** and **clinical trial**).

**Outcome:** a change in the health of an individual, group of people, or population that is attributable to treatment or a series of treatments.

**Outcome measure:** an *instrument* or *measure* developed by physicians and/or researchers to assess and quantify an outcome (see **instrument, measure,** and **outcome**).

**Patient research partner (PRP):** a person with a relevant disease who operates as active research team members on an equal basis with professional researchers, adding the benefit of their experiential knowledge to any phase of the project.

**Patient-reported outcome (PRO):** any report of a patient's change in health condition (outcome) or experience with health condition that comes directly from the *patient*, themselves. This is in contrast to a physician-reported outcome which is objectively measured by a physician or investigator. Patient-reported outcomes are measured with patient-reported outcome measures (PROMs) (see **outcome, physician-reported outcome,** and **patient-reported outcome measures**).

**Patient-reported outcome measure (PROM):** a measure or instrument that a patient uses to report on their experience with their health condition; an instrument or measure used to report patient-reported outcomes (PROs) (see **outcome** and **patient-reported outcomes**).

**Physician-reported outcome:** any report of a patient's change in health condition (outcome) or experience with health condition that comes from a physician or investigator. This is in contrast to a patient-reported outcome (PRO) which is subjectively reported by the patient (see **outcome** and **patient-reported outcomes**).

**Placebo:** the inactive drug given to the control group in a clinical trial (see **control group** and **clinical trial**).

**Predictive validity:** the degree to which instrument scores correlate (exhibit a mutually similar relationship) with scores of a *gold standard* measure at a *future* point in time; can this instrument *predict* the scores of a gold standard instrument? A type of criterion validity (see **gold standard** and **criterion validity**).

**Protocol:** the plan or set of steps to be followed in a study.

**Psychometrics:** the science of measuring mental capacities and processes (see **clinimetrics**).

**Quality of Life:** the standard of health, comfort, and happiness experienced by an individual (see **health-related quality of life**).

**Randomized controlled trial (RCT):** an experiment in which investigators randomly place subjects who meet *eligibility criteria* into either *treatment group* or a *control group*. Randomly assigning subjects to groups reduces *bias*. Also called a randomized clinical trial (see **clinical trial, eligibility criteria, treatment group, control group,** and **bias**).

**Reliability:** the ability of an instrument to produce consistent results; the consistency of a measure; the extent to which a measure is free of error. The three

types of reliability are internal consistency, intra-rater, and inter-rater reliability (see **internal consistency, intra-rater reliability,** and **inter-rater reliability**).

**Responsiveness:** the ability of a measure to detect *clinically important change* in a disease (outcome) over time. Considered a measure of validity over time. (see **minimal clinical important difference (MCID), outcome,** and **validity**).

**Sign:** a manifestation of a medical disease that is objectively observed by a physician or investigator. Examples of signs include erythema (redness), induration (thickness), and scaling of a psoriasis plaque. This is in contrast to a symptom (see **symptom**). Psoriasis signs is a patient-reported outcome (PRO) and IDEOM domains included in the Core Outcome Set (see **patient-reported outcome, outcome, domain,** and **Core Outcome Set**).

**Statistically significant:** a change caused by a treatment (outcome) that has a low likelihood of occurring by changes and, thus, can be considered a real difference.

**Smallest detectable change (SDC):** the smallest difference in an outcome that can be statistically detected in a given study. Also known as the **minimal detectable change (MDC)**.

**Symptom:** a manifestation of a medical disease that is subjectively observed by the patient. Examples of symptoms include pain, itching, or burning. This is in contrast to a sign (see **sign**). Psoriasis and psoriatic arthritis symptoms is a physician-reported outcome and IDEOM domains included in the Core Outcome Set (see **outcome, domain,** and **Core Outcome Set**).

**Systematic review:** a summative collection and critical appraisal of multiple published research studies to answer a specific research question with the best evidence available. Similar to a meta-analysis in that data from several studies are combined to reach a conclusion. Differs from meta-analysis in that no statistical methods are applied to this data to reach this conclusion (see **meta-analysis**).

**Treatment group:** the study group in a clinical trial that is given the active study drug (*not* placebo). Outcomes in the *treatment group* are compared to outcomes in the *control group* (which received the inactive drug or placebo). This minimizes *bias* by discerning which outcomes are due to the real effect of the treatment versus those that are caused by natural background variation in the way patients feel (see **clinical trial, placebo, outcome,** and **control group**).

**Treatment satisfaction:** the degree to which the patient perceives the treatment fulfills their health needs. Treatment satisfaction is patient-reported outcome and IDEOM domains included in the Core Outcome Set (see **patient-reported outcome, domain,** and **Core Outcome Set**).

**Validity:** the ability of an instrument to measure what it intends to measure; the truth or accuracy of the measure. Types of validity include content validity, criterion validity, construct validity, and responsiveness (see **content validity, criterion validity, construct validity,** and **responsiveness**)

## Abbreviations:

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| ACORN | Acne Core Outcomes Research Network |
| AUC | Area Under the Curve |
| BMQ | Beliefs about Medicines Questionnaire |
| BSA | Body Surface Area |
| BPSS | Beer Sheva Psoriasis Seveirty Scale |
| CDLQI | Children's Dermatology Life Quality Index |
| CSP | Children's Scalpdex in Psoriasis |
| COMET | Core Outcome Measures for Effectiveness Trials |
| COS | Core Outcome Set |
| COSMIN | COnsesnus-based Standards or the selection of health status Measurement Instruments |
| DIDS | Dermatology Index of Disease Severity |
| DIT | Desired Improvement Tool |
| HRQoL | Health Related Quality of Life |
| HISTORIC | HIdradenitis SuppuraTiva cOReoutcomes set International Collaboration |
| ICC | Intraclass Correlation Coefficient |
| IDEOM | International DErmatology Outcome Measures |
| IGA | investigator Global Assessment |
| LS-PGA | Lattice System-Physician Global Assessment |
| MCID | Minimal Clinical Important Difference |
| MDC | Minimal Detectable Change |

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| NAPPA-PBI | Nail Assessment in Psoriasis and Psoriatic Arthritis- Patient Benefit Index (NAPPA-PBI) |
| NPI-PS | National Psoriasis Foundation-Psoriasis Score |
| NRS | Numeric Rating Scale |
| PACE | Psoriatic Arthritis Screening Evaluation |
| PASI | Psoriasis Area Severity Index |
| PBI | Patient Benefit Index |
| PedsQL | Pediatric Quality of Life Inventory |
| PEST | Psoriasis Epidemiology Screening Tool |
| PGA | Physician Global Assessment |
| PGAxBSA | Product of physician global assessment and body surface area |
| PhGA | Physician Global Assessment |
| PPQ | Patient Preference Questionnaire |
| PRO | Patient Reported Outcome |
| proSPI | Professional-Simplified Psoriasis Index |
| PROMs | Patient Reported Outcome Measures |
| PSAID | Psoriatic Arthritis Impact of Disease |
| PsoSat | Psoriasis Satisfaction Questionnaire |
| PtGA | Patient Global Assessment |
| RAPID | Routine Assessment of Patient Index Data |
| REFLETS | REFlective evaluation of psoriasis Efficacy of Treatment and Severity |
| saSPI | Self assessment-Simplified Psoriasis Index |
| SDC | Smallest Detectable Change |
| SDD | Smallest Detectable Difference |
| SPI | Simplified Psoriasis Index |
| SSWTPQ | Spanish Satisfaction With Treatment of Psoriasis Questionnaire |
| TOPAS | Toronto Psoriatic Arthritis Screen 2 |
| TSQM | Treatment Satisfaction Questionnaire for Medication |
| TTAQ | Topical Therapy Adherence Questionnaire |
| VAS | Visual Analogue Scale |

## Sources:

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