**Biomarker** – a characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions.

**Susceptibility/risk biomarkers** – a characteristic that is measured as an indicator of the potential of a person to develop a disease or a medical condition, who currently does not have a clinically evident disease or a disorder.

**Diagnostic biomarkers** - a characteristic that is measured as an indicator of the existence of a disease or condition of interest, or to recognize individuals with the disease subtype.

**Prognostic biomarkers** – a characteristic that is measured as an indicator of the probability of a clinical occurrence, recurrence of disease, or worsening in patients with an unusual illness or medical condition.

**Monitoring biomarkers** – a characteristic that is measured as an indicator of the status of the disease or medical condition on exposure of or effect of a medical substance or an environmental agent.

**Predictive biomarkers**– a characteristic that is measured as an indicator of individuals who are more likely to experience a favorable or unfavorable effect from exposure to a medicinal product or an environmental agent than similar individuals without the biomarker.

**Pharmacodynamic/response biomarkers** – a characteristic that is measured as an indicator of a biological response has occurred in an individual exposed to a medicinal product or to an environmental agent.

**Safety biomarkers** – a characteristic that is measured as an indicator of the probability, occurrence, or degree of an adverse effect of toxicity on exposure to a medicinal product or an environmental agent.