

Classification of research and development activities of pharmaceutical and biopharmaceutical products

	Small molecules	Biologic products	Generics	Biosimilars
Basic research * ¹ (fundamental research)	Search for new therapeutic targets**	Search for new therapeutic targets**	-	-
Applied research *** (industrial research)	Library design, molecule screening, preclinical research	Cloning of human genetic material, cell banking, library design, molecule screening, preclinical research	development of new manufacturing process of active substance based on innovative ***** synthesis, tests on polymorphic forms of active substance leading to development of new pharmaceutical form of known pharmaceutical product	research and preclinical development of new biosimilar product
Early development phase **** (experimental development)	Clinical trials of phase I to IIIa (including phase 0)	Clinical trials of phase I to IIIa (including phase 0)	development of new formulation, new pharmaceutical form of known pharmaceutical product (active substance), bioequivalence studies	development of new formulation, new pharmaceutical form of known biological product and conduct of clinical trials
Late development phase ¹ (experimental development)	Phase IIIb of clinical trials (initiated after submission of application for marketing approval)	Phase IIIb of clinical trials (initiated after submission of application for marketing approval)	-	Phase IIIb of clinical trials (initiated after submission of application for marketing approval of biosimilar product)
Post approval activities ¹	Phase IV of clinical trials Safety studies Non-interventional studies	Phase IV of clinical trials Safety studies Non-interventional studies	Phase IV of clinical trials Non-interventional studies	Phase IV of clinical trials Safety studies Non-interventional studies

* in brackets classification based on "Community framework for state aid research and development and innovation" C 323/1, 30 Dec 2006.

**search for new therapeutic target can also be pursued for commercial reasons – in that case studies should not be classified as basic, but rather applied research or even early development phase.

**** development of new method of preclinical tests for commercial purposes may also be classified as early development phase.

*** also including studies confirming validity of animal model of the disease developed solely for commercial purposes, experimental breeding of genetically modified laboratory animals serving as animal model of a disease.

*****considering current development status of science and synthesis techniques.

¹ Wskazane badania nie są objęte wsparciem w ramach konkursu 1/1.1.1/2016