

PROVIDER PROFILE

Name of the organisation	Paul-Ehrlich-Institut (PEI)
Type of the organisation	National Competent Authority
Contact email(s)	innovation@pei.de
Offering website	www.pei.de
Service language(s)	German, English
Target group	Academic Principal Investigators/Groups/Consortia, SMEs, Big Pharma
Short support description	<p>Pre-Advice (offered free of charge):</p> <ul style="list-style-type: none">• Very early stage of development• General (scientific) guidance and regulatory orientation• Informal exchange on general issues with regard to the medicinal product class <p>Scientific Advice (connected to costs):</p> <ul style="list-style-type: none">• Specific project/product related aspects• Focus on quality, non-clinic and/or clinic• Questions concerning the planning and procedure of a clinical trial• Participation of further agencies/bodies may be possible (HTA, NCA, ethics committees)

For the national project initiatives DKTK and DZIF, the same advice structure applies, i.e. Pre-Advice organised as Kick-off meeting and Scientific Advice is within the regular scope.

This profile is part of the [Comprehensive Inventory \(CI\)](#) provided by the [STARS project](#).

Purpose of the CI is to assist European academic drug developers in finding support on regulatory affairs. The inventory lists various support services provided by national competent authorities, public actors and private entities.

For information about the STARS project please visit www.csa-stars.eu or contact CoordinationSTARS@bfarm.de.