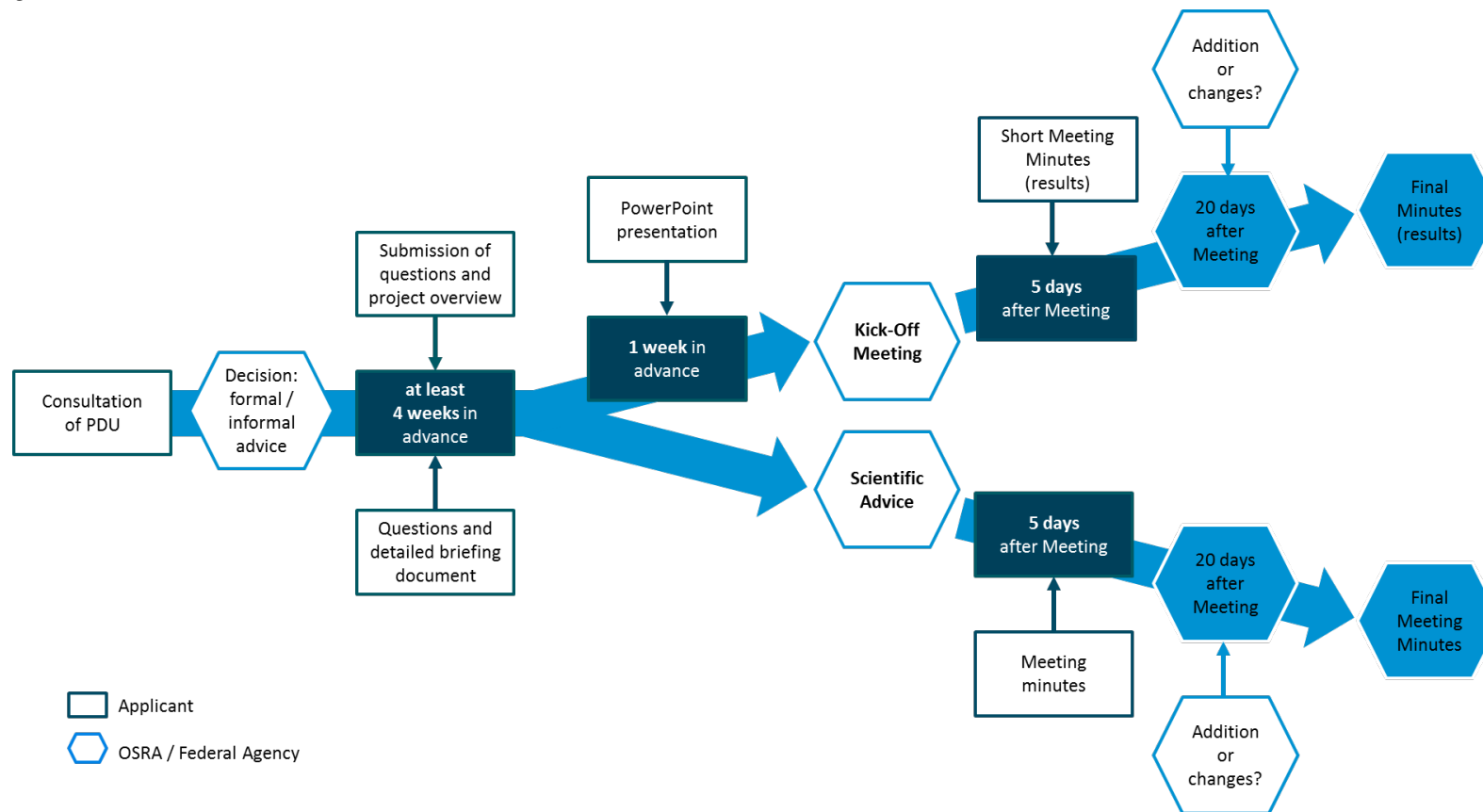


BfArM & PEI Kick-off and Scientific Advice Meetings

	DZIF Kick-off Meetings	Scientific Advice Meetings
Short Description	Informal project presentation	Scientific advice meeting adhering to federal agency's formal standards on structure and content
Aim	<ul style="list-style-type: none"> • Short presentation of project idea by applicant • Identification of regulatory questions • Reference to relevant guidance documents • Preparation of a scientific advice meeting 	<ul style="list-style-type: none"> • Short presentation of project by applicant • Discussion of submitted questions with regard to the applicant's position provided in the briefing document • Answer to submitted questions
Meeting-Structure	„Unstructured“; Open scientific discussion	Structured; Answers to submitted questions
Application	No –Meeting scheduled via OSRA/TPMO	Yes – via application form
Precise list of questions	No	Yes
Documents for application	At least four weeks in advance: Short project description and questions One week in advance: PowerPoint presentation and list of attendees Applicant should share the presentation at the meeting	At least four weeks in advance: <ul style="list-style-type: none"> • request form • cover letter • list of questions • detailed briefing documents containing background information and all relevant data • applicants position (including rationale) to submitted questions • list of attendees Presentation to be prepared for meeting
Expenses of assessors	Moderate	High
Protocol	Short summary of the results	Meeting minutes
Fees: AMGKostV	No	Yes (Fees paid by applicant) Please see for BfArM: AMG-KostV and for PEI: PEIKostV
Further information	BfArM: https://www.bfarm.de/EN/BfArM/Tasks/Advice-procedures/_node.html;jsessionid=18E78579C7E3E576A19FB5A13655315E.intranet262 PEI: https://www.pei.de/DE/regulation/beratung/beratung-node.html	

Flow chart:



Contact:

OSRA (BfArM):

Dr. Nils Lilienthal
 Dr. Miriam Fürst-Wilmes
 Dr. Michael Schramm

OSRA (PEI):

Dr. Nadine Kirsch-Stefan
 Dr. Sarah Altrichter-Dünnes
 Sabine Stemler

TPMO:

Dr. Thomas Hesterkamp
 Dr. Marina Steindorff
 Dr. Silke Alt

TPMO-VAC:

Dr. Sebastian Goy
 Dr. Simon Schröder

Email: OSRA@dzif.de

Email: TPMO@dzif.de