EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Approaching the Agency

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Briefing meetings with the Innovation Task Force

- Informal face-to-face meeting with regulatory experts
- At any time
- Applicant submits questions and data
- No assessment of data and no written response
- No costs.

Procedures with the Scientific Advice Working Party

Scientific advice	Qualification advice/opinion
Product and indication specific	For methodologies across indications or products
Fixed timelines – 40 or 70 days	Flexible timelines and proceedings
Applicant can have a face-to-face meeting if requested by the SAWP, mainly in case of disagreement with the proposal	Always face-to-face meetings, applicant can raise issues for discussion during the procedure
SAWP "looks" into the data but focuses on methodology	Assessment of the data!
Applicant receives written response Always confidential	Applicant receives written response Public if a positive opinion is issued (after agreement with the Applicant)

The qualification team and the committees

- One Coordinator and several team members selected according to scientific expertise needed (regulators and academia) and one EMA scientific staff
- SAWP – role
  - Discusses and agrees the conclusions of the Qualification Team
- CHMP involvement
  - Qualification Advices and Qualification Opinions are presented to the CHMP, the Committee discusses and adopts, response signed by CHMP Chair
  - Applicant includes the adopted Advice/Opinion in the future Marketing Authorisation Application.

Advice or Opinion?

- **CHMP Qualification Advice** on future protocols and methods for further method development towards qualification, based on the evaluation of the scientific rationale and on preliminary data submitted.

- **CHMP Qualification Opinion** on the acceptability of a specific use of the proposed method (e.g. use of a genomic biomarker or an imaging method) in a research and development context for regulatory purpose, based on the assessment of submitted data (agreed in a previous Qualification Advice or submitted directly fro qualification).

The value of pre-submission meetings

- Pre-submission meetings are strongly recommended:
  - Help you decide when and whether to formally start the procedure
  - Help with identifying the right questions and scope of request
  - Help with the amount and type of data to be submitted
  - Help clarify your strategy and give you directions

Use the scientific staff at the EMA

anytime - before, during or after a procedure for:

- Scientific, procedural and administrative support
- Informal teleconferences and meetings
- Help in the organisational matters, expert meetings, out-of-the-procedure meetings and scientific discussions
- Single contact point: links to other EMA groups