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Community Research

Adverse Drug Reaction Research

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Adverse Drug Reaction Research

- State of play in FP7
- Lessons learned from 2 calls
- What next?
- Projects funded and in the pipeline
- 4th call

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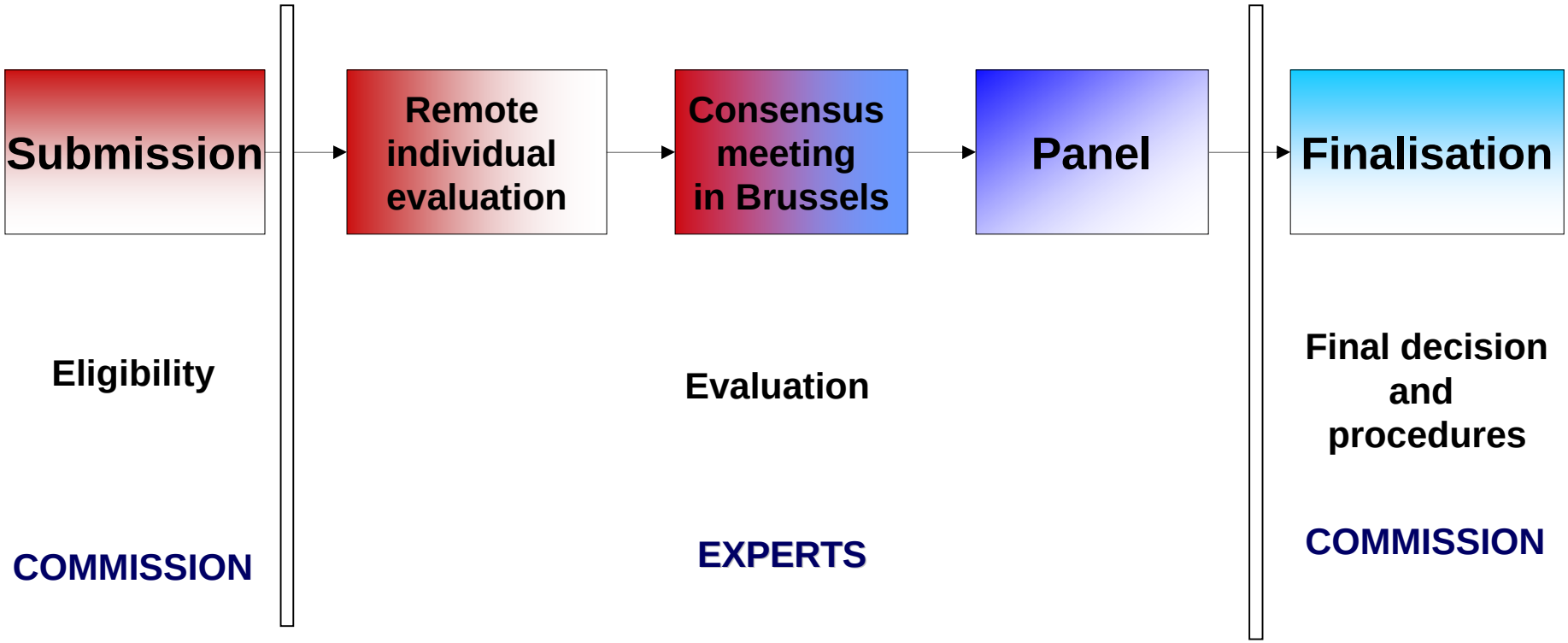
General overview of Evaluation process



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Evaluation criteria

- **adapted to each funding scheme and to each thematic area**
- **Three criteria:**
  - S&T Quality **(relevant to the topic of the call)**
    - Ø ***Concept, objective, work-plan***
  - Implementation
    - Ø ***Individual participants and consortium as a whole***
    - Ø ***Allocation of resources***
  - Impact
    - Ø ***Contribution to expected impacts listed in work programme***
    - Ø ***Plans for dissemination/exploitation***

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Proposal scoring

- **Each criterion is scored 0-5**
  - **use whole range**
  - **half-scores allowed**
- **Threshold is 3 for each individual criterion**
- **Overall threshold is 10**
  i.e. higher than the sum of the individual thresholds
- **Scores must pass *all thresholds*** for a proposal to be considered for funding

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Interpretation of Scores

5	**Excellent.** The proposal successfully addresses all relevant aspects of the criterion in question. Any shortcomings are minor.
4	**Good.** The proposal addresses the criterion well, although certain improvements are possible.
3	**Fair.** While the proposal broadly addresses the criterion, there are significant weaknesses that would need correcting.
2	**Poor.** There are serious inherent weaknesses in relation to the criterion in question.
1	**Very poor.** The criterion is addressed in a cursory and unsatisfactory manner.
0	The proposal fails to address the criterion under examination or cannot be judged due to missing or incomplete information

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Scores and Comments

Rules for scoring:

1. **Half marks may be given**
2. **The numerical average of marks for individual evaluations is only a first indication** è **the final consensus score may differ after discussion**, (added value of the discussion), **providing due justification**
3. **Comments must be consistent with the scores**
4. **If budget cuts are recommended – must provide clear justification and details about why and where** (what should be taken out from the work proposed etc.)

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Adverse Drug Reaction Research – 2nd Call

HEALTH-2007-4.2-2: Relative safety of non-steroidal anti-inflammatory drugs (NSAIDs).

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Results from 2nd Call

- **5 Proposals received**
- **1 proposal over all evaluation thresholds**
- **1 retained for funding**

- Good coverage of the topic listed.
- Few SMEs
- New Member States not represented!!

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Results from 2nd Call

SOS - Safety of Non-Steroidal Anti inflammatory Drugs

- Assesses the relative cardiovascular (CVD) and gastrointestinal (GI) safety of non-steroidal anti-inflammatory drugs (NSAIDs).
- Studies 4 national databaseses, comprising 35.000.000 subjects
- Will yield risk estimates for CVD and GI bleeding for each individual NSAID by dose and duration and by other important effect modifiers (e.g. aspirin use).
- Separate models built for children
- Other : results of the literature reviews, analysis of observational databases and re-analysis of published studies
- Result : decision model to support treatment and regulatory decisions

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Adverse Drug Reaction Research – 3rd Call

HEALTH-2009-4.2-2: Study of the Arrhythmogenic potential of different classes of medicines (FP7-HEALTH-2009-single-stage)

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Results from 3rd Call

- **2 Proposals received**
- **1 proposal over all evaluation thresholds**
- **1 retained for funding**

- Good coverage of the topic listed.
- Few SMEs
- New Member States not represented!!

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Results from 3rd Call

ARITMO : Arrhythmogenic Potential of Drugs

Assess the arrhythmogenic potential of antipsychotics, antihistamines and anti-infectives (> 250 compounds) via:

- Literature reviews of in-vitro and in-vivo preclinical evidence; conducting in-silico modelling to predict the arrhythmic potential
- Healthcare DBs reviews of 27 million persons in 5 countries to calculate rates and relative risks of arrhythmic events during drug use.
- Blood samples from cases and drug-matched controls,
- Information analysis from existing studies to assess the association between drug use and various arrhythmia outcomes
- Result : Ranked list of drugs according to arrhythmogenic potential allowing for more informed treatment and decision-making

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Adverse Drug Reaction Research – 4th Call

Funding scheme: Collaborative Project (Small or medium-scale focused research projects).
EC contribution: max. EUR 3 000 000. >1 project can be selected from each of the following themes:

- **Long-term effects in children and in young adults of methylphenidate in the treatment of attention deficit hyperactivity disorder (ADHD)**
- **Long-term adverse effects of immunomodulators (monoclonal antibodies)**
- **Long-term adverse skeletal effects of bisphosphonates.**
- **Medicine use in pregnancy (design of effective pregnancy prevention programmes, recommendations for safe use in pregnancy)**
- **Suicidal behaviour in relation to certain drug use (antidepressants, antipsychotics, varenicline, montelukast).**
- **Safety aspects of antipsychotics in demented patients.**

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SMEs : Commission Regulation (EC) No 2049/2005

- Administrative and procedural assistance from the SME Office at EMEA;
- Fee reductions for scientific advice, inspections and (for veterinary medicines) establishment of maximum residue limits;
- Fee exemptions for certain administrative services of the EMEA;
- Deferral of the fee payable for an application for marketing authorisation or related inspection;
- Conditional fee exemption where scientific advice is followed and a marketing authorisation application is not successful;
- Assistance with translations of the product information documents submitted in the application for marketing authorisation.

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SMEs

To determine which companies are eligible for SME incentives, the EMEA will apply the definition of micro, small and medium-sized enterprises provided in Commission Recommendation 2003/361/EC

EMEA : http://www.emea.eu.int
E-mail : smeoffice@emea.eu.int

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  http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.CooperationCallsPage&id_activity=1

- **Work Programme, incl. Adverse Drug Reaction Research :**

  http://cordis.europa.eu/fp7/dc/index.cfm?fuseaction=UserSite.CooperationDetailsCallPage&call_id=10

- **Independent Expert registration**

  https://cordis.europa.eu/emmfp7/index.cfm?fuseaction=wel.welcome

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