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Innovative Medicines Initiative

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European Medicines Agency

- Given the CAMD and IMI summarizes of work-scope just presented, do you see the gaps that are not being addressed, but would be critical to advancing the Alzheimer's disease initiatives?

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SAWP

CHMP
(Committee for Human Medicinal Products)

COMP
(Committee for Orphan Medicinal Products)

HMPC
(Committee for Herbal Medicinal Products)

PDCO
(Paediatric Committee)

CAT
(Committee for Advanced Therapy Medicinal Products)

PRAC
(Pharmacovigilance Risk Assessment Committee)

efpia

- The next step is how to translate the scientific language to a regulators language

- We need to find a 'context of use' for all the hard work that you have done to qualify their use in regulatory development, so adding meaningful context to pre-clinical and clinical development.

- All the information needs to be used because as it's necessary for fast-tracking and facilitating evaluation and approval

- What opportunities do you see for synergy/ leveraging both efforts?

- Qualification procedure cover new methodologies not only biomarkers – modelling and simulation, clinical reported outcomes, biomarkers in preclinical and clinical
- We will encourage IMI consortiums to ask for fee reduction if they have an SME as part of the consortium - will be able to pay only 10 % of the fee

- Given the global scale of this disease we all agree that information and data "sharing" is critical. (Whether it is sharing across companies or PPP's). Do you view sharing of information as a continued challenge and if so what can be done to improve the environment?
- The qualifications opinions - transparent
- We work close to the FDA in qualification procedure particularly in relation with clinical outcomes assessments

- What do you see as the regulatory impact of these efforts and/or areas of future focus; "harmonization of efforts" What is the role of standardization and harmonization of biomarkers and endpoints in AD?
- For a new drug to have a claim disease modification of AD a drug will need to have standardised biomarkers by the time MAA

- Have we done enough to empower/include/enthuse the public/patients/caregivers and if not how might we?
- Patients representatives are involved in the qualification procedures of Alzheimer's disease

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European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 22 January 2009
Doc. Ref. EMEA/CHMP/SAWP/72894/2008 Corr[1]

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

QUALIFICATION OF NOVEL METHODOLOGIES FOR DRUG DEVELOPMENT: GUIDANCE TO APPLICANTS

DRAFT AGREED BY SAWP	27 February 2008
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	24 April 2008
END OF CONSULTATION (DEADLINE FOR COMMENTS)	30 June 2008
FINAL AGREED BY CHMP	22 January 2009

efpia

- Presubmission phase with Scientific Administrator and coordinator
- We guide the company or consortium about the questions to ask and the information necessary to support the company‘s position.
- Company will submit a brifing book with the question and the company‘s position with their information
- The **qualification team** dedicated for expertise and the SAWP will discuss the request and produce a list of questions with the requirements for further information

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17 November 2011
EMA/CHMP/SAWP/809208/2011
Committee for Medicinal Products for Human Use (CHMP)

Qualification opinion of low hippocampal volume (atrophy) by MRI for use in clinical trials for regulatory purpose - in pre-dementia stage of Alzheimer's disease

Agreed by Scientific Advice Working Party	1 September 2011
Adoption by CHMP for release for consultation	22 September 2011
End of consultation (deadline for comments)	1 November 2011
Adoption by CHMP	17 November 2011

Links

- **EMA guidance for companies requesting SA or PA** http://www.emea.europa.eu/pdfs/human/sciadvice/426001en.pdf
- **Qualification of novel methodologies for drug developments**
- http://www.emea.europa.eu/pdfs/human/biomarkers/7289408en.pdf
- **Scientific guidelines**
- Http://www.emea.europa.eu/htms/human/humanguidelines/background.htm

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