Disclaimer: The views expressed in this presentation are the personal views of the speaker and may not be understood or quoted as being made on behalf of or reflecting the position of the EMA or one of its committees or working parties.

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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?
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)
• 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 consortia 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
European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 22 January 2009
Doc. Ref. EMEA/CHMP/SAWP/72894/2008 Corr¹

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

QUALIFICATION OF NOVEL METHODOLOGIES FOR DRUG DEVELOPMENT:
GUIDANCE TO APPLICANTS

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<tr>
<td>DRAFT AGREED BY SAWP</td>
<td>27 February 2008</td>
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<tr>
<td>ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION</td>
<td>24 April 2008</td>
</tr>
<tr>
<td>END OF CONSULTATION (DEADLINE FOR COMMENTS)</td>
<td>30 June 2008</td>
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<tr>
<td>FINAL AGREED BY CHMP</td>
<td>22 January 2009</td>
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• 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 briefing 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.
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

<table>
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<tr>
<td>Adoption by CHMP for release for consultation</td>
<td>22 September 2011</td>
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<tr>
<td>End of consultation (deadline for comments)</td>
<td>1 November 2011</td>
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<tr>
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<td>17 November 2011</td>
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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

• Scientific guidelines
  • Http://www.emea.europa.eu/htms/human/humanguidelines/background.htm