Global Clinical Trials for Alzheimer's Disease: Chapter 8. The Regulatory Environment Surrounding Alzheimer's Disease Research: FDA and EMA Guidance

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Data from clinical trials in emerging markets are becoming a standard component of the regulatory package being provided to support pharmaceutical marketing authorizations including the FDA New Drug Application (NDA) and the EMA Marketing Authorization Application (MAA). In this chapter, the highlights of the requirements for Alzheimer’s disease interventions are summarized, including a review of trial enrichment strategies. The topic of acceptance of foreign clinical data is also reviewed.

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