Study Designs to Benefit Older Adults: Approaches to Early Phase Therapeutic Development

Regulatory Perspectives

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Disclosure Information

- This presentation reflects the views of the author and should not be construed to represent FDA's views or policies

- I have no financial relationships to disclose.

- I will not discuss any specific off label use and/or investigational use in my presentation.

Some Numbers to Ponder

Global	North American	United States
• 65 years or above – 9%	• 65 years or above – 17%	• By 2030, 70% of all new cancer diagnosis in patients 65 years or older

Trial median age is 6.5 years younger than disease population: Ethan. Ludmir et.al. JAMA Oncology, 5(12); 1769-1773, 2019

Patients with cancer over 80 years – 16%, Registration trial representation -4%:Bindu Kanapuru et. al. JCO, 35(15S); 2539-2539, 2017

What Will I Cover today?

- Regulatory Initiatives
- Early Phase Data to Support Inclusion of Older Adults in Cancer Clinical Trials
- Summary

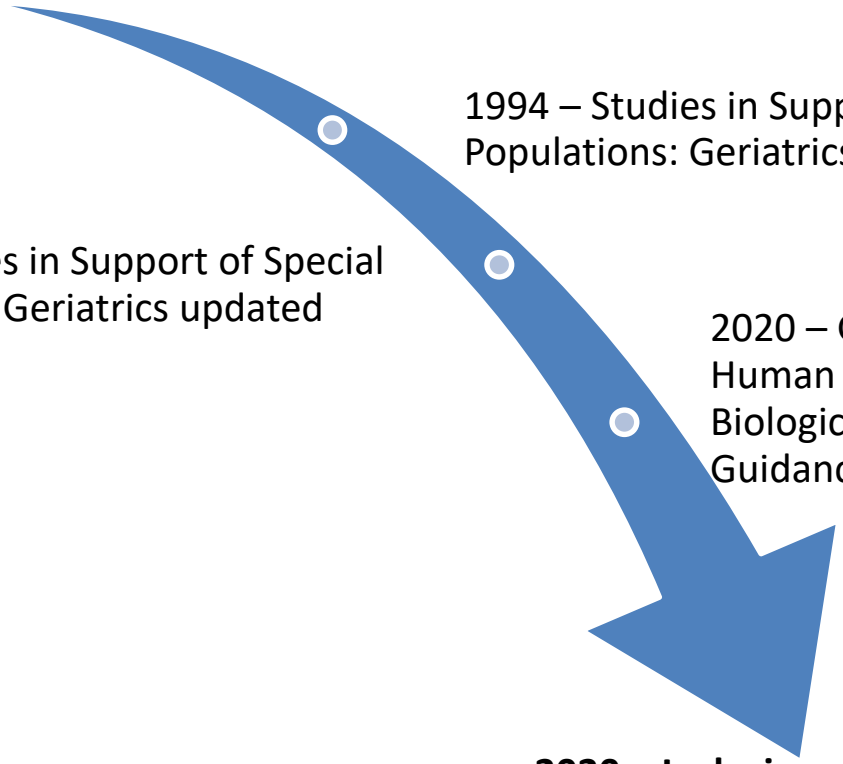
Regulatory Initiatives

1989 – Guideline for the Study of Drugs likely to be used in the Elderly

1994 – Studies in Support of Special Populations: Geriatrics (ICH E7)

2010 – E7 studies in Support of Special Populations: Geriatrics updated

2020 – Geriatric Information in Human Prescription Drug and Biological Product Labeling – Guidance for Industry (Draft)



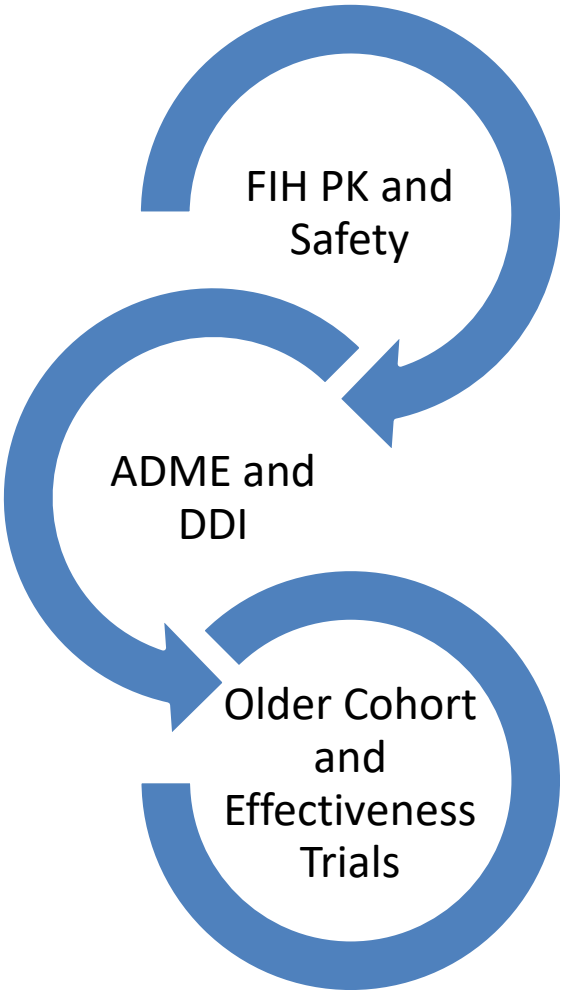
2020 – Inclusion of Older Adults in Cancer Clinical Trials (Draft)

Data Generated in Nonclinical Drug Development Program

- Nonclinical Animal Pharmacology
- Nonclinical Animal Toxicology
- In vitro drug metabolism pathways
- Identification of biomarkers

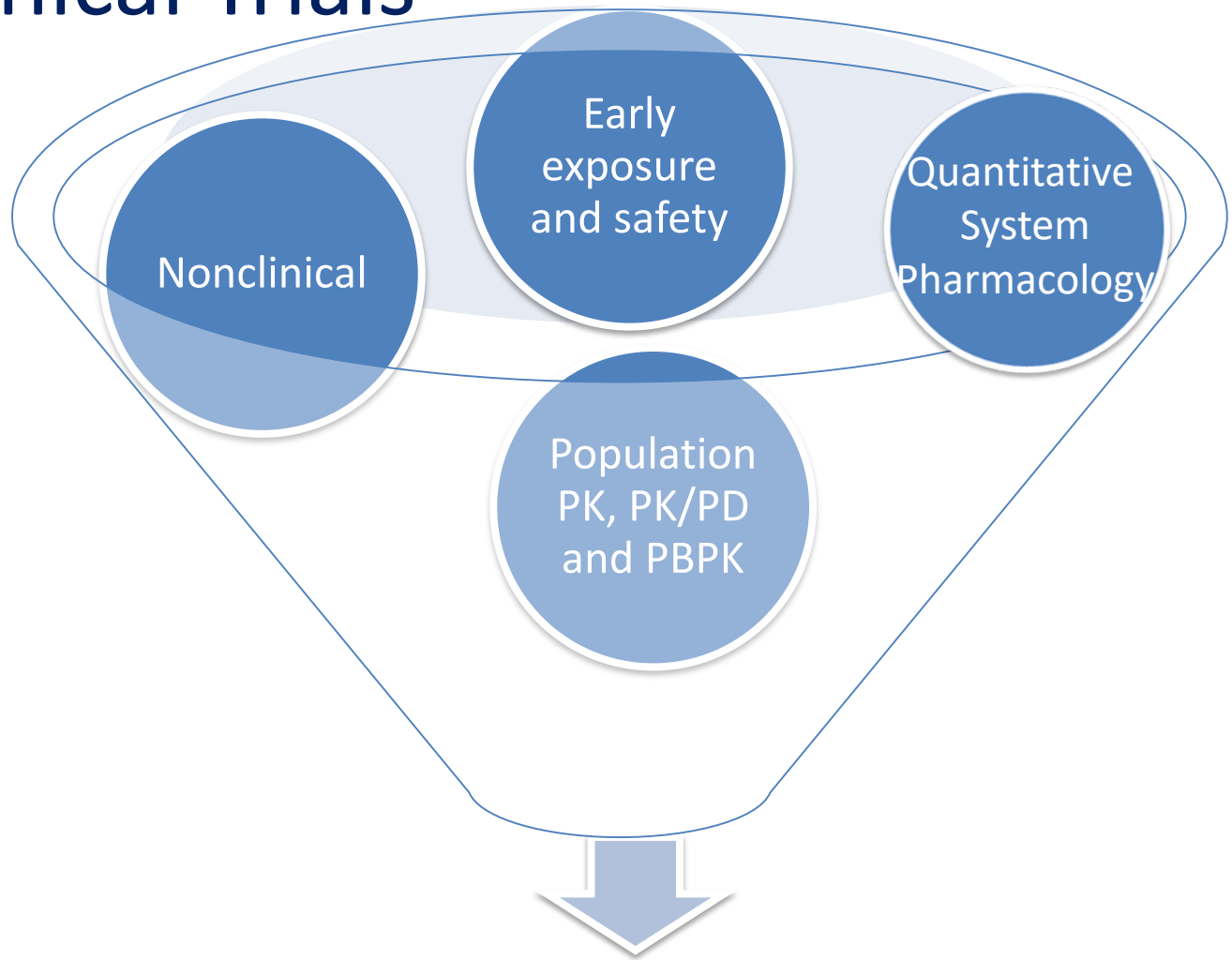
No specific animal study is conducted to assess impact of age on pharmacology and toxicology of a drug

Early Phase Clinical Trials



- First-in-human safety and PK trial
- Mass balance study establishing route of clearance
  Drug interaction studies
- Exposure in older cohorts
  Inclusion of older patients in effectiveness trials

Clinical and Nonclinical Information Supporting Inclusion of Older Patients in Clinical Trials



Summary

- Regulatory initiatives promote inclusion of older patients in clinical trials
- Data from the entire drug development program should be analyzed for safe inclusion of older patients in clinical trials
- Clinical Pharmacology data and tools can assess adaptive inclusion of older patients in various phases of clinical trials
- FDA, industry, and academics need to work together to change the landscape

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Thank you

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