Team 2 Presentation

-Chikungunya vaccine-

Prospective AVSS of a new Live attenuated Chikungunya Vaccine

in the elderly population

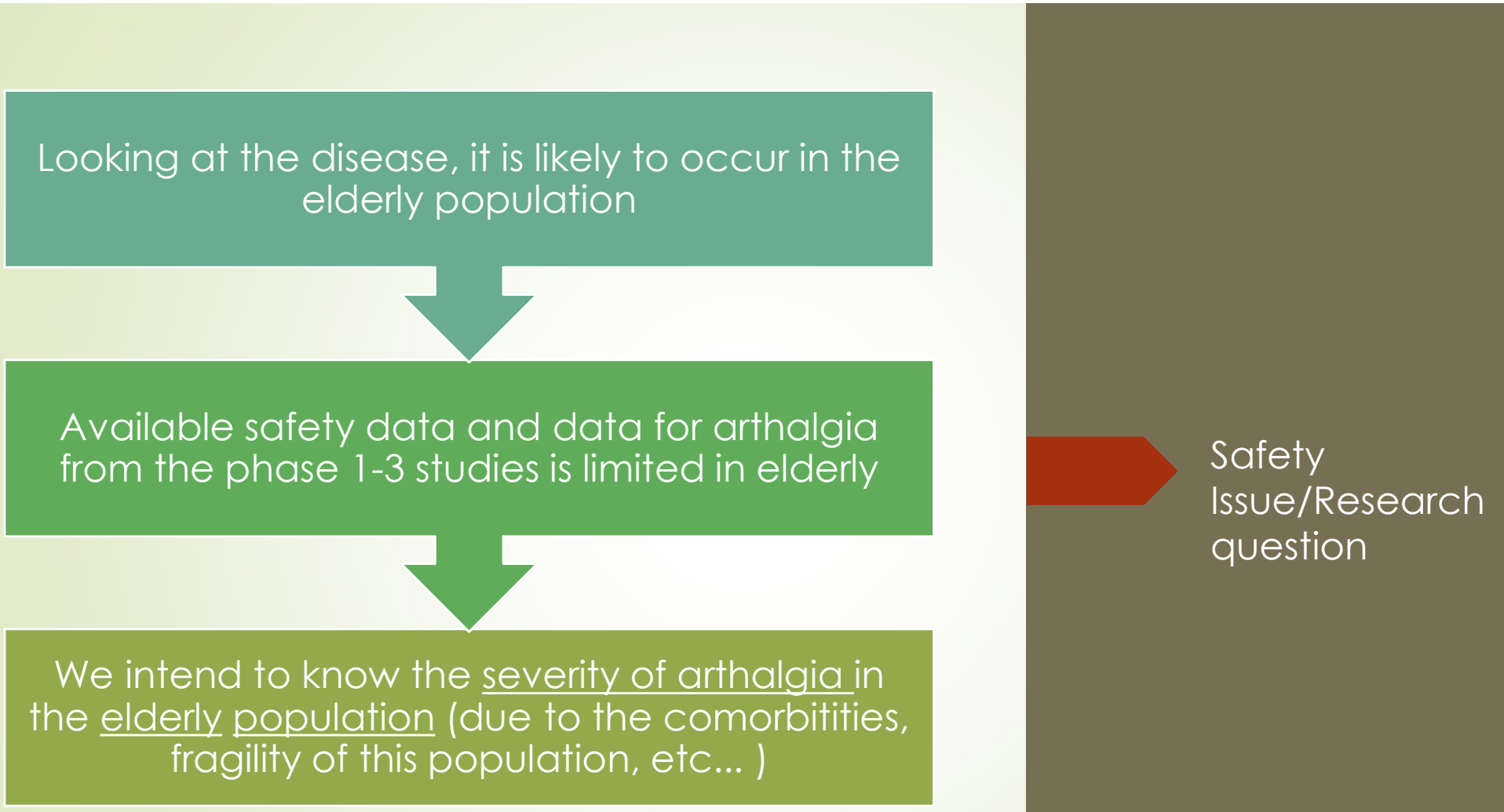
Team members

- Beauty Moloto (presenter)
- Beatriz Lucchesi (reporter)
- Katharina Hartmann (mentor)
- Dr Devang Patel
- Triana Rahmila
- Chetanraj Bhamare
- Shuyan Zuo
- Linda Nesbitt
- Antoine Diatta
- Sumit Tandon

Background

- Live attenuated vaccine and safety issues can be expected such as:
  - reverse of the virus,
  - the antibody enhanced disease,
  - AESI for chikungunya viral vaccines (SPEAC list),
  - Theoretical concerns based on the immunopathogenesis

- No safety concerns were reported, however available safety data and data for arthalgia is limited in elderly as only 10% of the population was exposed during the phase 1-3 trials are over 65 years
  - Looking at the disease, it is likely to occur in the elderly population
  - Arthalgia is the most prominant sympton and its debiliating in the elderly
  - Risk of chikungunya is higher for the elderly

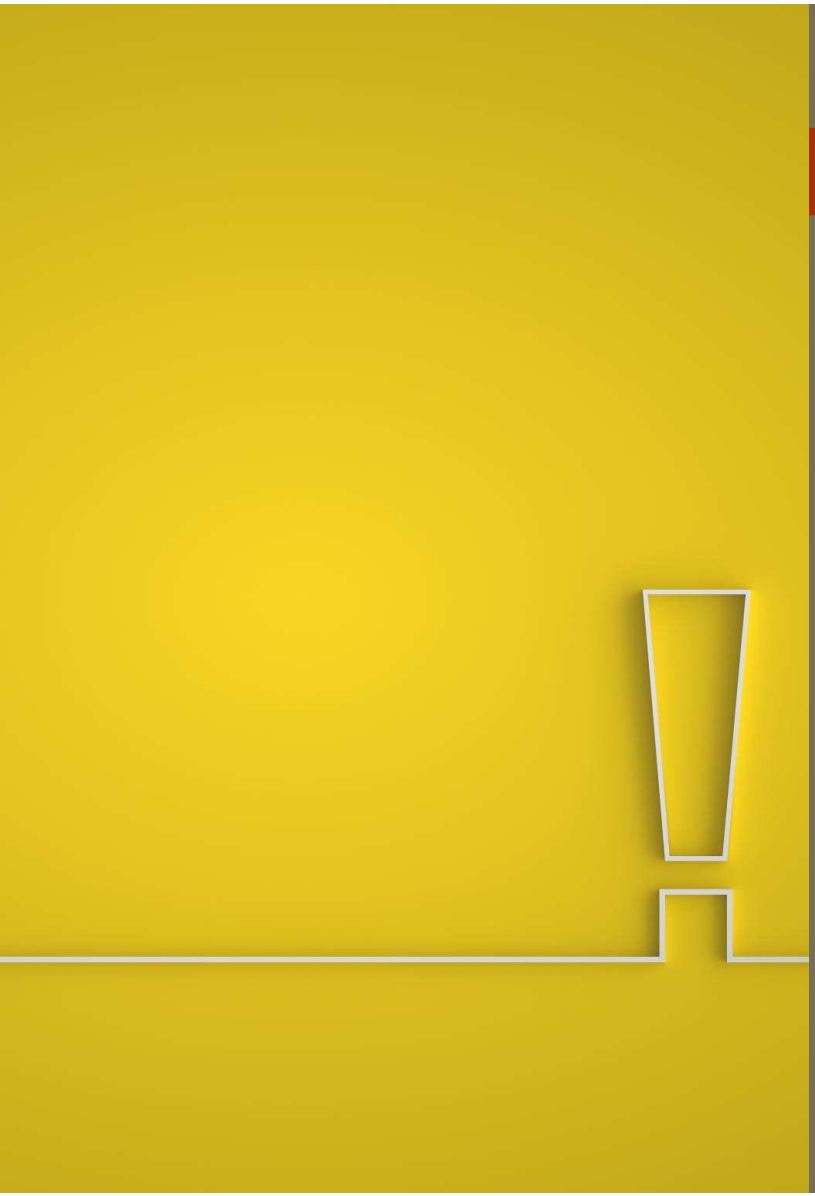

Looking at the disease, it is likely to occur in the elderly population
Available safety data and data for arthalgia from the phase 1-3 studies is limited in elderly
We intend to know the severity of arthalgia in the elderly population (due to the comorbitities, fragility of this population, etc...)
Safety Issue/Research question

Study design/methodology

- Study design cohort (multiple sites)
- Primary data collection
- Joint disorder, SAE, medically attended adverse events (MAAE)
- Duration of the study ~1.5 years
- Follow up frequency D0, D7, D14 and D28 and D42
- Data will be registered by the HCP in the clinical sites in the EDC and the sponsor will extract the data to analyse

Study Population

- ~3000 participants
- All individuals elegible for vaccination with > 60 years and older according to approved indication
- Willing partipant in the study and sign the ICF(Informed Consent Form)
- Non-exclusion criteria
- Participants will be enrolled at the time that they will be vaccinated



Outcomes desired

- To have the frequency (N and %) >Joint disorder
  >SAE
  >Medically attended Adverse Event
- Eldery age intervals > 60-69y; 70-79y; 80-89y; 90y)