Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Phase III Study for EU Mock-Up Licensure
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):
Authors/sponsors: Hartmut Ehrlich, Otfried Kistner/Baxter
Study Design (including the phase of clinical trial): Phase III

                                A/Indonesia/05/2005 or A/Vietnam1203/2004 - booster
Manufacturer: Baxter
    Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Inactivated whole virion, viruses produced in Vero cells
    Adjuvant: 
    Delivery system/site: IM
    Doses (antigen and adjuvant, number, in µg: 7.5 for priming and 3.75 or 7.5 for booster, Two vaccinations for priming at days 0 and 21

Study population: Adult, Elderly Number of subjects involved: 550     Age range: 18-59years and>60 years
    Health status: Healthy volunteers
    Special inclusion/exclusion criteria:

Clinical Endpoints Assessed
    Safety assessments:
    Immunogenicity assessments:
        immunoassay type
        HI (type of RBC used):
        NT (type of neutralization assay):
        SRH

Results
    Safety:
        Reactogenicity:
        AEs:
        SAEs:

    Immunogenicity
        HI or NT:
        GMTs:
        GMT Ratios (post:pre):
        Per cent responding (4 fold increase):
        Per cent responders at specified titer:
        NT≥20 after priming:
            adult     elderly
            day 42    day 100    day 42    day 100
            73%       40%        74%       40% 
        SRH:
        Per cent with titre (in mm²)

Current status of the clinical trial (completed, ongoing, in preparation):
Date envisaged for availability of results, if not yet available:

Planned time schedule for next phase of development: