

### CRF design (10 points)

According to the “QUADRIFLU” project, you have design the data including visits, domains, and variables to be collected in the study. Please design a Case Record Form (CRF) only for “Screening” and “Enrollment” visits according to domains and variables defined in the first week.

Year of study.....

Subject ID:.....

Study site ID:.....

#### Screening visits

1. Gender:  Male       Female
2. Year of birth: .....
3. Age (years):  18-30     31-40       41-50       51-60       >60
4. For female (Male can skip this question):  Pregnancy (or Positive for pregnancy test)  
 Lactating                       Un-pregnancy (or Negative for pregnancy test)
5. Vaccination:  Receive any vaccine within 4 weeks  
  
 Plan to receive vaccine during 3 weeks  
  
 Received influenza vaccine in the past 6 months  
  
 Had influenza illness in the past 6 months
6. Body temperature:   $\leq 37^{\circ}\text{C}$       $> 37^{\circ}\text{C}$  (Chronic illness)
7. Able to attend all scheduled visits and to comply with all trial procedures:  No  Yes

Interviewer signature.....

Date of data collection...../...../.....

Year of study.....

Subject No:.....

Study site ID:.....

**Enrollment visits**

• **General Data**

1. Informed consent was done:  No  Yes

2. Gender:  Male  Female

3. Age (years):  18-30  31-40  41-50  51-60  >60

4. Physical examination:

Height.....cm. Weight.....kg. Blood pressure:...../.....mmHg.

Respiratory rate.....breaths/min.

Body temperature:   $\leq 37\text{ }^{\circ}\text{C}$    $> 37\text{ }^{\circ}\text{C}$  (Chronic illness)

5. Medical history:  No  Yes is .....

6. Drug presently use:  No  Yes is .....

• **Vaccination test**

7. Blood collection (before injection):  No  Yes

8. Single dose vaccination test:  QIV (Quadrivalent inactivated influenza vaccine)

TIV (Trivalent inactivated influenza vaccine)

9. Diary card record:  No  Yes

10. Immunogenicity test:  No  Yes

**Interviewer signature**.....

Date of data collection...../...../.....