

EMWA Professional Development Programme

## **An Overview of Healthy Volunteer Studies**

**Drug Development – Foundation: Duration – 3 hours**

**Anne McDonough, McDonough Clinical Research Ltd**

### **Pre-workshop assignment**

#### **Objective**

To introduce the unique aspects of studies in healthy volunteers (as opposed to clinical trials in patients)

#### **Content**

Read the following documents:

- (1) ICH Topic E8 General Considerations for Clinical Trials  
[https://database.ich.org/sites/default/files/E8\\_Guideline.pdf](https://database.ich.org/sites/default/files/E8_Guideline.pdf)
- (2) The life of a professional guinea pig: What it's like to earn a living as a research subject in clinical trials – Cari Romm – The Atlantic – Sep 23, 2015  
<http://www.theatlantic.com/science/archive/2015/09/life-of-a-professional-guinea-pig/406018/>

To ensure that the workshop corresponds to your needs, please answer the following questions:

- (1) What is your current job?
- (2) How much experience do you have in medical writing for healthy volunteer studies?
- (3) Based on the reading materials above, which 3 questions would you most like to see answered during the workshop? (Questions must be within the scope of the workshop as described in the abstract.)

#### **Assessment criteria**

None.

#### **Instructions**

Read the documents listed above. To qualify for credit for the workshop, complete the questions above and e-mail to Anne McDonough by Friday, 29 October 2021 (Anne@McDonoughCR.com).

#### **Resources and materials**

None.

#### **Time required**

1 hour