EMWA Professional Development Programme

Writing a Clinical Study Protocol (DDF41)

Workshop Status: Foundation (3 hours)

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Pre-workshop assignment

Objective
The purpose of the pre-workshop assignment is to start the process of picturing the study and describing it.

Content
The main part of the pre-workshop assignment is to draw a flow chart.

In addition, you should download a copy of ICH E6(R2) and read Section 6: Clinical Trial Protocol and Protocol Amendment(s).

Assessment criteria
You will receive some feedback on your assignment and you are likely to gain more from the workshop if you have completed it. You are also required to submit a pre-workshop assignment if you wish to be eligible for credit for the workshop.

Instructions
The following overview of study design is a brief description of a proposed clinical study:

Overview of Study Design

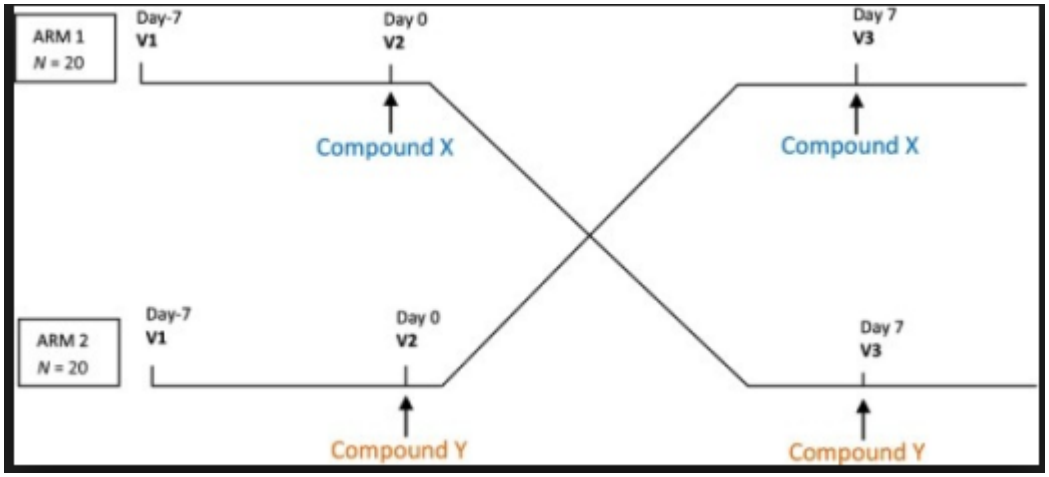
The study is a randomised double-blind, single-centre crossover study in subjects with persistent allergic rhinitis with two, 4-week active treatment periods separated by a 2-week placebo washout period.

Following a screening visit and a placebo run-in period of at least 2 weeks, eligible subjects will be randomised to 4 weeks of treatment with either fluticasone propionate aqueous nasal spray (FP) or beclomethasone dipropionate aqueous nasal spray (BDP). At the end of the first active treatment period, there will be a placebo washout period of at least 2 weeks. Subjects will then cross over to use the alternative nasal spray, i.e. BDP or FP nasal spray during the second active treatment period.

Visits will be scheduled at 4, 6, and 10 weeks after randomisation to assess safety and efficacy. Individual subjects' participation will be a minimum of 12 weeks.

Using this information, draw a flow chart (pictorial representation) to illustrate the flow of the study. If you are not familiar with protocols, you can find examples such

as the one below by searching Google for "study flow diagram crossover study" or similar.



Note: please do not provide a tabular schedule of assessments.

Please send the completed assignment by e-mail to mail@debbiejordan.co.uk AND info@wendykingdom.com. The deadline for submission is 02 November 2020.

Resources and materials

ICH E6(R2). Just type "ICH E6(R2)" into any search engine and you will find it, e.g. at https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf

Time required

Up to 3 hours.