UNIVERSITY OF MONTENEGRO
FACULTY OF PHILOLOGY

ENGLISH FOR SPECIFIC PURPOSES – PHARMACY

Podgorica, 26.05.2016.

Complete the table using a word from the text in exercise 1.

verb		document		intend		inform
noun	permission		administration		formulation	

permit
documentation
administer

intention
formulate
information

permit
documentation
administer

intention
formulate
information

Miki is informing a new trainee about what she has learned regarding a certain investigational drug at Vine Pharmaceuticals. Complete the excerpt using the correct form of the words in exercise 4.

First of all, it is the _____[1] of the company to complete the preclinical trials by the end of the year. After that, regulatory agencies have to give _____[2] to commence with the clinical testing in humans, which is also done at our company. But before that can happen, our scientists determine how to _____[3] the active pharmaceutical ingredient into a suitable administration form. We have to _____[4] each step of every test very thoroughly before the regulatory agencies give their approval to proceed to the next stage. The _____[5] must show that the _____[6] of the investigational drug is safe for our subjects.

5 1 intention
2 permission
3 formulate

4 document
5 documentation
6 formulation

UNIT 4, EXERCISE 5

First of all, it is the **intention** (1) of the company to complete the preclinical trials by the end of the year. After that, regulatory agencies have to give **permission** (2) to commence with the clinical testing in humans, which is also done at our company. But before that can happen, our scientists determine how to **formulate** (3) the active pharmaceutical ingredient into a suitable administration form. We have to **document** (4) each step of every test very thoroughly before the regulatory agencies give their approval to proceed to the next stage. The **documentation** (5) must show that the **formulation** (6) of the investigational drug is safe for our subjects.

DESCRIBING A PROCESS (PART 1)

The passive is often used to describe a process. We use it because it focuses on the action, rather than on the person or thing (agent) doing the action. Often the agent is unclear, unknown, or irrelevant.

An experiment A trial/study	is/was	carried out/conducted/done/performed.
A drug		absorbed/administered/formulated/manufactured/ prescribed/taken.
The data	are/were	provided/transmitted.
A number of experiments Several tests		conducted/done/performed.
The criteria	can must be will	met.
A study		carried out/ conducted/done/performed.

HOW TO FORM PASSIVE VOICE:

VERB TO BE + PAST PARTICIPLE

AM, IS, ARE, WAS, WERE, *ED/III COLUMN*

CAN BE, MUST BE, WILL BE

6 Complete the sentences about preclinical development using the correct form of the verbs in the box.

be administered • be conducted • be determined • be formulated • be provided • be used

1 We started the trial after tests on investigational drugs _____ in vivo and in vitro over a period of up to five years.

2 Last year, results of preclinical testing _____ to come up with the best formulation of the intended drug.

3 Extensive documentation must _____ to the appropriate regulatory authorities.

4 A drug intended to act on the skin can _____ as a cream.

5 Potential risks to humans _____ in toxicity studies.

6 The requirements of drug bioavailability determine how it will _____ to humans.

1 were conducted
2 were used
3 be provided
4 be formulated
5 are/were determined
6 be administered

Linda	Good morning, everybody.
Jake	Hi, Roger. Hi, Miki. How's the internship going? Still enjoying your stay here?
Miki	Yes, thanks. Everyone has been very helpful.
Jake	Roger, could you please fill me in on what this is about?
Roger	Certainly, Jake. Well, hi, everyone. Do take a seat! I suggest that Linda first tell us what problem she observed. I hear you noticed something wrong with the dogs that got the new drug. Is that correct?
Linda	Yes, it is. This morning when I wanted to take the blood and urine samples, I saw that some of the dogs had been vomiting. They looked pretty bad.
Miki	You said – some of the dogs. Does that mean they are not all affected?
Linda	That's right. Some of them had vomited and were still retching, whereas the others appeared to be fit and healthy.
Roger	Is the reaction restricted to any particular dosage group?
Linda	As far as I can tell, the control and low-dose groups are not affected at all. The animals affected are only in the high-dose group.
Jake	So, that pretty much means the drug substance is the cause. What did the study in rodents show?

Linda	There were none of these reactions, but, of course, rats can't vomit. There were no clinical findings at all, not even chewing – which is a clinical finding in rats. You can read all the details in the study report.
Jake	If you ask me, I think we should consider using mini-pigs instead of dogs, since they're not as sensitive.
Roger	I'm not sure I agree with you on that. How long have the dogs been treated with the substance?
Linda	For two days now and the individual doses were adjusted to the most recently recorded body weight.
Jake	It seems to be the concentration of the drug. So we'd better cancel the highest dose, if the dogs are too sensitive.
Miki	If we did that, would the complete study protocol have to be changed?
Roger	Yes, it would. But first we need to figure out which dose we are going to use and then write the amendment. Personally, I would prefer to

keep going for another three days – without the high-dose group, of course. In the meantime, just carry on with the other groups and I'll let you know what we come up with after talking to the study director. Please inform me immediately if any other animals start showing similar symptoms. Also, could you please send me a copy of your report on the clinical observations as soon as possible?

Linda Sure, no problem. Miki, would you like to help me with that?

Miki Yes, I've never done that before.

7

1 F – She discovered it herself.
2 T
3 F – Only animals in the high-dose group are affected.
4 T
5 T
6 (–) – He only says he will talk to the study director, but not when.
7 F – She is going to help Linda.

GETTING INFORMATION AND MAKING SUGGESTIONS

Asking for and clarifying information	Making suggestions	Responding to suggestions
Could somebody fill me in on ... ?	I suggest making ...	I'll let you know what we come up with.
I'd like to know what has happened.	I suggest we take ...	I'm not sure I agree with you on that.
Does that mean ... ?	We could consider trying ...	
I have heard ... . Is that correct?	So, we'd better test ...	

Unscramble the words. Make questions or sentences to ask for and clarify information, make suggestions, and respond to suggestions. Note that each time there is one word you do not need.

1 fill in me Could somebody is what on the problem there's please ?

_____

2 correct does it the dogs Is responding that aren't to the drug

_____

3 need to figure we which animal group First, out is receiving what concentration

_____

4 could We consider testing group without another animals of

_____

5 would know to prefer mini-pigs I use dogs instead of Personally,

_____

6 later know we come with I'll trials let up you what

_____

7 we put have the would to I change study protocol imagine

_____

8

1 Could somebody (please) fill me in on what the problem is(, please)?
2 Is it correct that the dogs aren't responding to the drug?
3 First, we need to figure out which animal group is receiving what concentration.
4 We could consider testing another group of animals.
5 Personally, I would prefer to use (dogs/mini-pigs) instead of (mini-pigs/dogs).
6 I'll let you know (later) what we come up with (later).
7 I imagine we would have to change the study protocol.

LINKING IDEAS

Certain words are added to make additional points, or to compare or contrast ideas.

Adding a relevant point	**Making a comparison or a contrast**
In addition,/Additionally, ...	... , whereas ...
... not only... , but also ...	... , while
Besides, ...	... (even) though
Furthermore, ...	However, .../But ...

12 **Use the word or phrase in brackets to link the two ideas. In some cases you will still have two sentences.**

1 There were no clinical findings in the mid-dose group. The high-dose-group animals showed clinical symptoms. (while)

2 The pulse rate was increased. The blood pressure was high. (not only ... but also)

3 There were no clinical findings in the oral administration studies. There were clinical findings in the intravenous-dose studies. (however)

4 Mini-pigs are easy to handle. Rhesus monkeys are difficult to work with. (whereas)

5 The drug was well tolerated by rats. It did not have any effect on blood pressure. (furthermore)

12 1 While there were no clinical findings in the mid-dose group, the high-dose group animals showed clinical symptoms.

2 Not only was the pulse rate increased, but also the blood pressure was high.

3 There were no clinical findings in the oral administration studies. However, there were clinical findings in the intravenous-dose studies.

4 Mini-pigs are easy to handle, whereas rhesus monkeys are difficult to work with.

5 The drug was well tolerated by rats. Furthermore, it did not have any effect on blood pressure.

Dear Miki

At lunch yesterday you asked me to send you some general information on clinical trials. Here is a rough summary that might be useful.

Phase I Trials: These are studies which are performed to evaluate the safety of drugs in healthy people, and to determine the pharmacological properties of drugs. They are done to find out how the drug reacts in the body. Toxicity, metabolism, absorption, and excretion are observed and documented.

Phase II Trials: These are controlled studies conducted to evaluate the effectiveness of the drug in a particular indication and to determine possible side effects and risks. These studies are performed on volunteers and a number of patients with the target disease or disorder. In this phase, testing determines the safety and efficacy of the drug in treating the condition and establishes the minimum and maximum effective dose.

Phase III Trials: After gaining evidence that the drug is effective, these controlled and uncontrolled trials are carried out to obtain additional information to evaluate the overall benefit–risk relationship of the drug. In this phase, a large group of patients is studied and closely monitored by physicians for efficacy and any adverse events after long-term exposure to the drug.

Phase IV Trials: These are post-marketing studies after getting approval for general sale. They are carried out in order to gather further information about the drug's safety, efficacy, and optimal use.

Hope this helps. Call me if you need anything else.

Best wishes

Jill

Which phase does each description belongs to?

1 Phase _____ is performed after there is preliminary evidence that the drug is effective.

2 In phase _____, the lowest and highest doses are determined.

3 Phase _____ is the first phase in which patients with the target disease or disorder take part.

4 In phase _____, further information regarding the ideal use of the drug is collected.

5 Phase _____ is the final phase before getting marketing approval.

1 III 2 II 3 II 4 IV 5 III

INSIDE CLINICAL TRIALS

An adverse event is any abnormal medical occurrence in a patient or clinical trial subject after a medicinal product has been administered. It does not necessarily have a causal relationship with the medicinal product.

Adverse reaction refers to all abnormal and unintended responses to an investigational medicinal product related to any dose administered.

In a **controlled study**, one group of test subjects is exposed to the substance, while the control group is not. Test subjects in the treatment group receive the medication under study, whereas the control group receives either a standard medication or a placebo. The results are then compared to determine the health effects of the substance being studied. **Uncontrolled clinical trials** do not have a comparison group.

4 The clinical trials for RFI 100089 were successful and the documents can be submitted. For this reason, Vine Pharmaceuticals has arranged a mock inspection to prepare for an upcoming visit by the regulatory authorities. Listen to part of the inspection and circle the correct ending to the sentences below.

1 The inspector wants to look at
   a an instruction manual.
   b the detailed data gathered during the clinical trial.

2 The inspector
   a did not accept the documentation about the change in temperature.
   b considered the incorrect change to the documentation to be minor.

3 In order to solve the problem
   a the temperature was increased.
   b the temperature was decreased.

UNIT 4, EXERCISE 14

Inspector All right. May I have a look at your documentation now?

Expert Yes, of course. Here it is.

Inspector Where can I find details of storage temperatures?

Expert If you check the third page, you'll find them at the bottom of the page.

Inspector I'm afraid I can't read the original text, as the original information has been made illegible. You know, it should only be crossed out with a single line so that the original text can still be read. Who is responsible for that? You know this is a deviation, don't you? More of these could result in a major finding.

Expert Yes, and we certainly don't want that. Umm, let me see. It's initialled and dated by Dr Frensen. He's new here. But I see here on this document that he has now had training, so you can rest assured that this won't happen again.

Inspector	Well, I'll accept that, since training has been done. Just make sure that all changes are made according to Good Manufacturing Practice standards and you will prevent major findings.
Expert	You're right.
Inspector	So, how do you account for the temperature change?
Expert	You mean, the changes we made in the storage temperature? Is that right?
Inspector	That's correct.
Expert	The reason for that is simple. Our stability studies showed that the storage temperature had an unwanted effect on the substance. The original temperature was too high, which led to a value that was outside the standard curve.
Inspector	All right, that sounds plausible. Let's move on to the safety regulations. I would like to start with the documentation of the safety training of the staff.

15 **Who would say this during an inspection, the expert (E) or the inspector (I)?**

1 I'll send for that immediately. ☐

2 How do you account for the change? ☐

3 You can rest assured that this won't happen again. ☐

4 If you check page six you'll find it at the bottom of the page. ☐

5 It was initialled and dated by Dr Svenson. ☐

6 Where can I find the change that was made? ☐

18 **The following words are often confused. Put the correct one into the sentences. If necessary, look back in the unit. At least one word of each pair has been used in this unit.**

illness/disease

1 There is a history of lung _____ in the family.

2 He missed five days of work because of _____.

sensitive/sensible

3 Dogs are more _____ to drugs than mini-pigs.

4 It was a _____ decision to cancel the trial.

affect/effect

5 I felt the _____ of the new ointment right away.

6 The active ingredient currently being tested seems to _____ the kidneys.

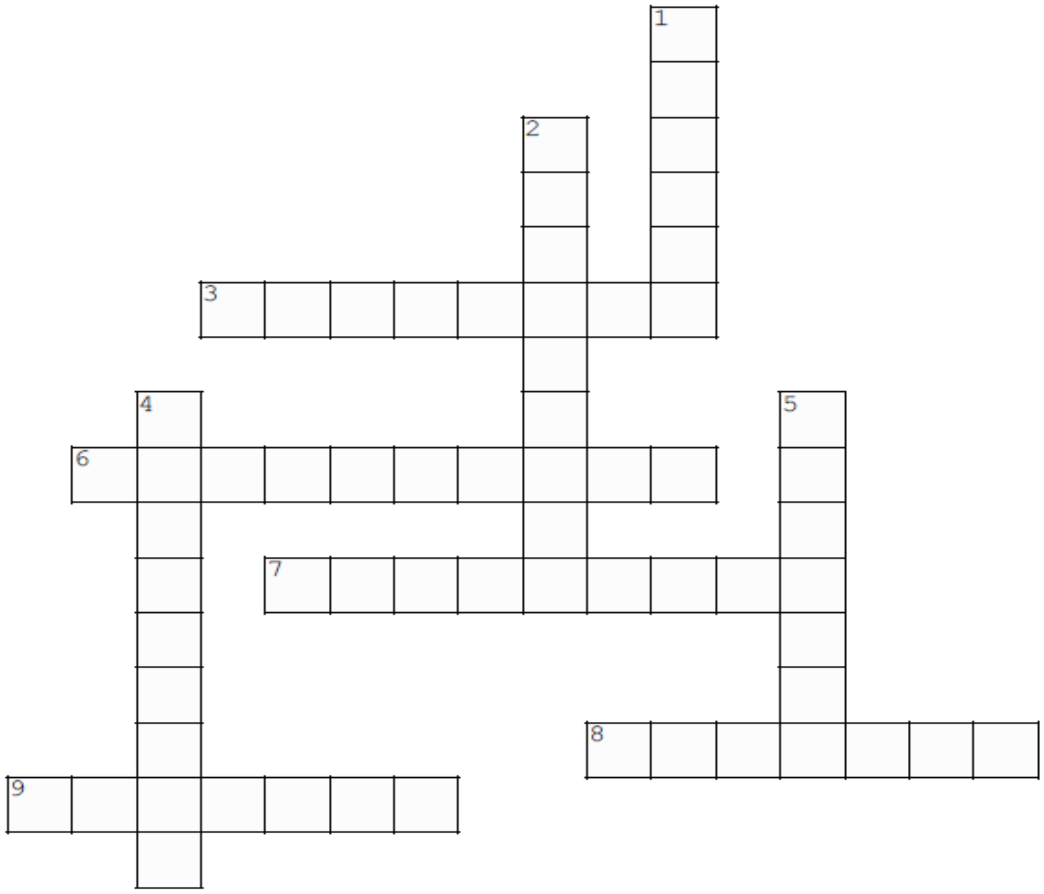
shortly/briefly

7 The adverse event occurred _____ after the injection.

8 The trial director spoke _____ to his staff about the current status of the trial.

1 disease
2 illness
3 sensitive
4 sensible
5 effect
6 affect
7 shortly
8 briefly

Complete the crossword below



Across

3. a thick smooth substance that you put on sore or injured skin
6. the right to do something that is given to you by someone in authority; you need this if you want to commence the trial
7. very large in amount or degree, with a lot of details
8. in a way that does not take much time or give many details
9. negative, unpleasant, or harmful

Down

1. to have an effect
2. a plan in your mind to do something
4. reacting quickly or strongly to something
5. an illness that affects people or animals, especially one that is caused by infection

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ACROSS:

OINTMENT
PERMISSION
EXTENSIVE
BRIEFLY
ADVERSE

DOWN:

AFFECT
INTENTION
SENSITIVE
DISEASE

ZAVRŠNI ISPIT – FORMAT ISPITA

1) prevod odlomaka tekstova
2) ubaciti odgovarajuci termin/frazu u rečenicu
3) passive (na principu vjezbe 6, na strani 42)
4) spojiti lijevu i desnu stranu da bi se dobila recenica ili objasnio
neki pojam
(poput vjezbe 10 na strani 45)


That's all Folks!

THAT'S ALL FOLKS.
THANK YOU FOR COMING!
SEE YOU ON JUNE 11.