

**RANZCP Auckland Training Programme**  
**Mock Objective Structured Clinical Examination**

**Station No. 3**

**Sept 2006**

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**Station No. 3 - Introduction and Aims**

This station concerns the ability to interact appropriately with a pharmaceutical company representative.

The main aim of this station:

The candidate must engage in discussion with a pharmaceutical company representative, maintain ethical boundaries, and discuss issues regarding prescribing, research trials and sponsorship.

Candidate must demonstrate

- Ability to interact professionally;
- Ability to discuss the relationship of pharmaceutical companies with psychiatrists;
- Ability to discuss research trial principles;
- Ability to maintain appropriate boundaries regarding product sample and sponsorship.

Requirements:

- Table and 2 chairs
- Actor for patient (female)
- Instructions for Candidate

Reference: RANZCP Ethical Guideline #5

### **Station No. 3 - Instructions to Candidate**

**You have seventeen (17) minutes to complete this station.**

You are an acute adult inpatient ward registrar who has agreed to meet with a pharmaceutical company representative to do a survey. You have not previously met the representative, who is new to the district.

You are aware that the representative wants to do a general survey of some sort with you, but also to talk to you about a new psychotropic medication "Vivrilax" which has recently been launched. You do not know anything about this medication, as yet.

You have managed to fit this meeting into a vacancy in your usual afternoon clinic.

As the most senior psychiatric registrar at the hospital, you have recently taken on the task of organising a local Journal Club, as there had been one but it has not really been functioning properly for a few months. You are keen to get it going again and to encourage attendance.

**Your tasks are to:**

- **Carry out the survey with the pharmaceutical representative**
- **Discuss the relationship of pharmaceutical companies with psychiatrists**
- **Discuss sponsorship with the pharmaceutical representative**
- **Discuss clinical trial organisation with the pharmaceutical representative**

### Station No. 3 - Instructions to Examiner

The examiner will indicate the appropriate seat to the candidate and will point out the *Candidate's Instructions*.

***“This is a copy of your instructions. Please proceed with your meeting.”***

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If the candidate asks any other questions about their task, refer them back to the *Candidate's Instructions* by saying

***“You have your instructions, please proceed.”***

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If the candidate says they are finished and want to leave the room, say:

***“You may leave the room, but please make sure that you have completed the station to your satisfaction, as you cannot come back in again.”***

Stand up and introduce yourself as soon as the examiner has shown the candidate their seat - shake hands with them. **Use your own name** and introduce yourself as “**the new local representative for Blackwell pharmaceuticals.**” “**Thanks very much for agreeing to see me - I really appreciate it as I know how busy you are**”. “**I promise that I won’t take up much of your time.**”

Explain that you have to do a general survey about the interface between psychiatrists and the pharmaceutical industry - **“we’re doing these with everyone at the moment”** but also that after the survey, you’d like to briefly give them some information about **“our new product Vivrilax”**.

**SURVEY:** (pretend to scribble actual responses down in note form but don't tire yourself out trying to do this properly. Say encouraging things intermittently like "excellent" "OK" "good", "that's great - we're almost there!" etc. Chat about their responses and draw them out - get them to explain their replies if they are brief and do not do so. )

- (“OK, great - pressing on”)***

- 3) Would you be interested in having more information about the management of sleep disorders in general? (and about any in particular?)
- 4) In what way do you think a pharmaceutical company could best provide you with information on this topic? (or any relevant psychopharmacological topic). Press them for more ideas if they come up with few. "Any other ways we could provide this?"

5) What are your views on the relationship between psychiatrists and the pharmaceutical industry? (if they need prompting - "should there be a relationship at all?")

- 6) What are your views about the involvement of psychiatrists in clinical trials organised by pharmaceutical companies? (Get them to go into quite a bit of detail here)

- 7) What would you say the key ethical issues are for psychiatrists, regarding the setting-up of such clinical trials? (encourage them to discuss this quite fully, and to offer several ethical issues. "OK - any other ethical issues?" etc.)

8) Would you be happy to rely on research findings from a trial organised by a pharmaceutical company and carried out by staff and psychiatrists employed by that company?

- if not, why not?
- if not, what other research evidence would you also want to see?

9) Would you be prepared to change your clinical practice based on the results of just one research trial? Why not, if not?

**(“OK, that’s great. Now, one final question, moving to a different issue.”)**

10) Are there any problems in a psychiatrist accepting pharmaceutical company sponsorship so as to attend an overseas conference?

a) Firstly - if they are a presenter? b) What if they weren’t presenting, just attending?

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**“Thank you VERY much for that, that’s the Survey all done.”** (If they ask you the purpose and use of the survey explain it’s “a market survey” and is “anonymous” and “not for publication”)  
**“Now, I understand that you’re organising a Journal Club here at the hospital?  
Can I be of any assistance? For example I could arrange to provide lunch?”**

If they decline this, get them to explain why it would be a problem.

If they explore your offer further or after more discussion, try to persuade them by explaining that you would plan to provide finger food, sandwiches and fruit, no alcohol, and to have a stand with information about your company’s products in one corner (“very unobtrusively”).

Offer to help circulate flyers about the Journal Club meetings to all participants. If asked about this, these would say “Meeting sponsored by Blackwell Pharmaceuticals”.

Offer to provide some speakers for the sessions. You would plan to arrange speakers who have been involved in psychopharmacology research within your company (you don’t really understand what a ‘Journal Club’ is - you can ask them to clarify this).

**“OK, well, just before I let you get back to the ward, because I know you’re busy, I have a datasheet about Vivrilax here. It’s a new non-addictive hypnotic and we’re quite excited about it. Now, I can also send you a couple of papers from the initial trials run by the company in Minneapolis (sorry I don’t have them with me today) - they were published in the company’s Pharm-Update - that’s our journal. Will those be enough?”**

If they request alternatives - (e.g. RCTs carried out by independent researchers and published in peer reviewed journals) say you will see what there is and get back to them, but you are not sure if any of that sort have been completed yet.

Then offer them a **“starter pack”** of samples of Vivrilax **“so you can see how effective it is”**.

If asked for more details about the drug, use the datasheet and go over the basic prescribing details with them. **“I’ll just leave this with you. But do call me if you’ve got any questions at all.”**

Finally, in the last few minutes, ask the registrar how they would set up a clinical trial on the ward. **“Before we finish, can I just ask you, as I’m pretty new to all this. How would you go about setting up a clinical trial here on the ward, to show that Vivrilax is more effective for sleep than a standard benzodiazepine - say compared to Lorazepam.”** Press them to describe the methodology of such a trial to you briefly, even if they say they wouldn’t do this themselves, especially focussing on how it could be “randomised”, on how patients would be selected for the trial and whether it would be a “controlled” trial (“like, a randomised controlled trial”).

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### **How to Play the Role**

Wear smart “Sales Representative” type of clothing. Be very pleasant, enthusiastic and friendly and thank them for their time intermittently. Start by calling the registrar “Dr Xxxx” etc. (they will have a name-badge) but ask if you can call them by their 1<sup>st</sup> name and do so if they agree.

You come from a prior sales rep job in medical equipment. You are new to the company and the “patch” and will be a bit vague about details and offer to **“find that out and I’ll get right back to you”** etc. Accept the registrar’s decisions - e.g. whether to accept Journal Club sponsorship or the “starter pack”. Chat about pros and cons as you’re curious & haven’t really thought about these issues before. Don’t be too pushy.

**MARKSHEET**  
**Station 3**

**1.0 APPROACH AND ETHICAL BOUNDARIES**

**Did the candidate demonstrate an appropriate professional approach to the company representative? (Proportionate value - 25% )**

Achieves the standard by a polite approach while maintaining appropriate ethical boundaries. Candidate should behave appropriately and show caution regarding acceptance of the "starter pack" and regarding company sponsorship of the Journal Club.

Surpasses standard if an especially adroit handling of the ethical and boundary issues is evident.

Does not achieve the standard if – is dismissive or impolite, or inappropriately relaxed in ethical boundaries - i.e. if they readily accept the starter pack without discussing that this might compromise their ability to prescribe the most appropriate medication for ward patients. Journal Club sponsorship can be accepted but only if the registrar says they will need to be explicit with attendees at meeting regarding the extent of the pharmaceutical company's sponsorship.

Category: Approach to meeting and rep	Surpasses Standard	Achieves Standard	Just below standard	Standard Not Achieved
ENTER GRADE (X) IN ONE BOX ONLY				

**2.0 DISCUSSION OF INVOLVEMENT IN CLINICAL TRIALS WITH THE INDUSTRY, AND ETHICAL ISSUES**

**Did the candidate adequately discuss the involvement of psychiatrists with the industry in clinical trials? (Proportionate value - 25% )**

Areas to be discussed include the clinical relevance of such trials, risks vs benefits for patients participating, and issues of patient consent and confidentiality. The need to fully inform patients about possible risks and benefits should be mentioned, and the need to obtain Ethics Committee approval. Need to follow various national and international guidelines regarding such trials may be covered. The need for independence of the researchers regarding the publishing of results should be mentioned, and that negative as well as positive results need to be published and company sponsorship acknowledged in any publication.

A candidate who surpasses the standard will cover this comprehensively, with a clear understanding of the ethical issues involved.

Does not achieve the standard if the discussion is inadequate with poor understanding of how such trials are organised or the ethical issues that arise.

Category: Involvement with industry in clinical trials	Surpasses Standard	Achieves Standard	Just below standard	Standard Not Achieved
ENTER GRADE (X) IN ONE BOX ONLY				

### 3.0 DISCUSSION OF THE RELATIONSHIP OF PSYCHIATRISTS WITH THE INDUSTRY

**Did the candidate carry out sensible, comprehensive discussion of this relationship?  
(Proportionate value - 25%)**

A balanced view is required, with acknowledgement that the pharmaceutical industry does provide important support and resourcing for a range of educational and research activities, yet mention of possible conflict of interest regarding the different motivations of the industry and of psychiatrists who have a different employer and a primary responsibility to patient care. There should be some breadth in the areas discussed - i.e. sponsorship of educational meetings, conferences and of research.

A candidate who surpasses the standard will discuss this very well and in a balanced manner.

Does not achieve the standard if the candidate lacks balance and is either entirely negative regarding the support and resources provided by the pharmaceutical industry or lacks an awareness of possible conflicts of interests and ethical issues, and of the primary responsibility of clinicians to patient wellbeing.

Category : relationship with industry	Surpasses Standard	Achieves Standard	Just below standard	Standard not Achieved
ENTER GRADE (X) IN ONE BOX ONLY				

### 4.0 DISCUSSION OF HOW TO ORGANISE A CLINICAL TRIAL ON THE ACUTE WARD

**Did the candidate adequately discuss the organisation and methodology of setting up such a trial on their ward?  
(Proportionate value - 25%)**

Candidate should demonstrate a reasonable knowledge about the methodology required, especially as regards patient selection and randomisation and the use of a comparison drug vs a placebo control. Issues raised by an acute inpatient setting should be mentioned, e.g. problems with informed consent due to patients being treated compulsorily. Note that in the limited time available, not *all* aspects of the methodology of such trials are expected to be covered.

A candidate who surpasses the standard will demonstrate a clear understanding of the methodology of such trials and potential issues in an acute setting, and will manage this discussion well.

Does not achieve the standard if a poor grasp is demonstrated regarding how to set up such trials or if the discussion takes no account of the particular issues in an acute inpatient setting.

Category : Discussion of clinical trial methodology	Surpasses Standard	Achieves Standard	Just below standard	Standard Not Achieved
ENTER GRADE (X) IN ONE BOX ONLY				

#### **Global Proficiency Rating**

Did the candidate demonstrate adequate overall knowledge and performance of the task?

Circle One Grade to Score	Definite Pass	Marginal Performance	Definite Fail
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