Tips and Guides

(I) Interview Tips for Freelance CRA positions

The purpose of a good CV is to get you noticed by the client. To achieve this goal your CV must contain relevant information related to the vacancy you are applying for. Remember, you need to put yourself in the shoes of the client who is sifting through many CVs to get to the ones that instantly make an impression on the person short listing for interview.

You have to demonstrate in your CV that you have the experience for the vacancy, the skills that the job requires and possibly the experience in the therapeutic area the client is seeking.

So if the position is for a freelance field based CRA, the Client would want to see a CV which –

- Runs in chronological order from your first job in a clinical research environment to becoming freelance consultant.
- Demonstrates clear dates – month / year of job career history with a clear date distinction when you became freelance.
- Highlights your duties/responsibilities in each position.

In addition, it is always a good idea to include a table of the studies undertaken.
An example of an experience table of studies with functions – see table 1.

Once you have been selected for an interview, the first (and sometimes only interview for a position) is a telephone interview. Many freelance positions that Klinikos are approached to fill are won on the strength of a telephone conversation alone as the client may not have the time or ability to see you face to face and therefore may make a decision based on how you come across at this interview.

Telephone Interviews

Be Prepared:

At this stage, the Client is trying to determine if you have the right credentials for the job. The interviewer is trying to gain information in many areas such as experience, commitment, confidence, language, organisation etc so it is important that you

- Are on time for the interview and in a relaxed, quiet environment safe from disturbances. – It is irritating if the line is poor or the connection broken
- Have a copy of your CV in front of you. – The Client will usually use your CV to check dates and positions held.
- Are enthusiastic about the vacancy. – Remember, it is a telephone interview and your personality and positive telephone manner needs to come through to the interviewer.
- Have knowledge of the Client's company. – It is always well received when you understand key aspects of the Client's core business.
- Are prepared to answer each question as fully as possible. - Remember more information is better than less as the interviewers will make their decisions based on the answers you give.
- Speak clearly and slowly – especially as the person calling may not be native to your country. – In this way any misunderstandings can be avoided.
- Have prepared answers to questions that are likely to be asked – see below

Typical Questions

- Briefly explain your career history from when you started in clinical research? – The interviewer wants to confirm your career to date so that your experience is clarified.
- What type of studies have you worked on? – it may be that the interviewer is really only interested in one particular therapeutic area – eg cardiovascular so information on as many studies (eg hypertension, heart failure, stent surgery etc) in this is area is important.
- When was your last GCP training? - Many clients want a candidate to have had refresher training within the last two years.
- What responsibilities have you had in these studies? – The more duties and responsibilities you have had will add to your experience and make the decision process for the interviewer easier. The list below is not exhaustive but many candidates fail to mention some of them at interview.

1. Ethics and/or Regulatory submissions
2. Amendments and Informed Consent writing.
3. Investigator budget control/payment management, courier/laboratory management.
4. Pre study, Initiation, monitoring, close downs.
5. Study management, CRA mentoring
6. Pre-study, initiation, Monitoring, Close-downs.

- What is your attitude to travel? – Many clients expect freelancers to travel to different geographical regions within one country so limiting your travel to one region may reduce your chances of success.

Questions you can ask

For Freelance positions, the client at the time of setting the interview may have had limited information on the project so it is perfectly reasonable to now ask about

- The type of project?
- Has the project started?
- How long is the contract for?
- Who would I be reporting to?
- What support is available within the company?
- What technology is used in the project – if any?

At the end of the Interview

Always finish the interview on a positive note by thanking the interviewer for their time and for this opportunity and if successful, what would be the next step.

Post Telephone Interview

Klinikos is always keen to know how an interview proceeded so please contact us as soon as possible so that we can have your feedback. This is important as the Client will contact us to give their feedback and very often if we have spoken to you first we can allay any potential concerns the Client may have by understanding your explanation of the issue.

For CRAs who are looking for their next position please contact Klinikos.

(II) Tips for Investigator Sites

What does it take to be a good Investigator Site? It really is common sense and should be to potential investigators who wish to be accepted by Pharmaceutical companies to conduct their clinical trials.

Unfortunately in our experience there are still many Investigator Sites that are only used once by a Sponsor and then dropped because their recruitment and or organisational abilities are poor.

It is a well known fact that 90% of studies fail to recruit on time because of problems at the Investigator Site and that is why recruitment times usually have to be extended or more investigators have to be selected and initiated – both having a cost implication to Sponsors.

Klinikos operates a group of GP Investigator Sites which have been pre qualified over the past number of years. Key criteria for being a "member" include -

- The PI being actively involved in the recruitment process and not just a figure head and be able to manage his/her team to maximise recruitment
- The PI must have support staff with sufficient time to assist in the research process and be fairly rewarded for their time.

To explain the above - if the PI is not "hands on", direction can often be lost leading to problems. If CRAs find problems at site, they need to know corrective actions will be taken by the PI and the team informed.

Our experience of sites that use support staff eg Research Nurses or Study Site Co-ordinators who perhaps have other duties at site eg - Practice Nurse can often lead to problems as staff feel they are not properly reimbursed for their time or allocated enough "protected time" for research. This often leads to friction within the team.

In addition, the site must be able to understand the needs and requirements of the Sponsor and indeed the CRAs who visit the site.

From the Sponsor's viewpoint –

- The site must be able demonstrate feasibility and a patient database relevant to the protocol.
- Once selected, the site must be able to recruit according to their target assumptions within the time frames agreed.
- The site must be able to demonstrate good organisational skills eg Site File maintenance, continual Essential Documentation filing, documentary evidence of recruitment and screening logs. – see section on Study File.
- More studies use Electronic Data Capture (EDC) and therefore sites have to maintain their understanding of this technology.
- The site must be able to accommodate the CRA for monitoring visits and understand the requirements at a monitoring visit.
- Sponsors require that the PI and study team members have undergone GCP training and this is maintained every two years.

Many years ago the Pharma industry used to simply ask if an Investigator could enrol patients into a particular trial. Now the question to a potential Investigator is “why should we select you as a site for this study?”

Experienced sites know this question will be asked at a pre study meeting by the Sponsor and are prepared in terms of previous metrics, database searches, previous study information. The more confident a Sponsor is about a Site, the more likely it will be accepted.

Many sites still fail to understand how to best accommodate the CRA (who is the “ambassador “ for the Sponsor and often decides whether the site will continue to chosen for future studies) for a monitoring visit. There have been many articles written on this subject but simply put, the site should recognise that the CRA is a visitor and has to get through a lot of work at this visit and does not want to be side tracked by missing data, lack of drug returns, poor source documentation.

The more organised a site is pre monitoring, the easier it is for the monitor to check study information and get through more CRFs and more importantly – the site will get paid sooner for the work that has been completed and checked by the Sponsor!

For Study Sites looking for Clinical Trial work - please contact Klinikos on 0141 952 1630