Tasks of a study nurse

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

☒ Consulting, Speaking honoraria

BARD, Medtronic, Spectranetics, Biotronik, Bayer Healthcare, Daiichi Sankyo, Intact Vascular, Profusa, Rexgenero,
Tasks of a study nurse/coordinator

Team at Division of Angiology, Medical University Graz, Austria [On behalf I’m giving the talk]

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Paul Gressenberger
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Tasks of a study nurse/coordinator

A study nurse/coordinator is familiar with the national and international formalities and conventions of everyday life in clinical trials and stands side by side with the investigator to achieve an expert working and a high quality in the performance of clinical trials.
Tasks of a study nurse/coordinator

Handling the patient

- Prescreening patients who might be eligible for the proposed protocol
- Screening patients who have been selected out of the prescreening process according to the in and exclusion criteria of the specific protocol in accordance with the PI or SPI

To assist the patients' relatives and explain them the protocol or answer their questions (they will be contacted by an uncertain potential participant within the 24 hour time frame you have to provide for written ICF or even worse after trial inclusion)

To create an atmosphere of confidence and trust

Never try to convince a study nurse to include a patient she/he does not qualify as eligible
Handling the patient

- Performance of follow up visits
- Long term contact person for study participants
  - [If they did a good job within the first trial, patients might come back for a subsequent one]
- Fixing dates for follow up visits
- Contacting patients if they are not coming back to FU visits in person and trying to collect as much information as possible to fulfill the study requirements
Tasks of a study nurse/coordinator

Handling Regulators

- Contact person for regulatory issues
  - Ethic committee submission and subsequent issues
  - Competent authorities submission and subsequent issues
  - Organizing contract process

Central contact between PI/Sub PI, Sponsor, EC, CRO and competent authorities
Tasks of a study nurse/coordinator

Data management

- Data collection and data documentation
- Data entry [eCRF/paperCRF]
  - Challenge
    - changing eCRF’s over duration of trial
    - consistent change of platforms
    - repeated training sessions for eCRF handling
    - new requirements for new and add on data acquisition over duration of trial
- Storage of study documents for 15 yrs
Tasks of a study nurse/coordinator

Data management

- AE and SAE notification
  - Challenge
    - To define AE/SAE
    - To keep the timelines of notification
- Preparation and Post processing of audits, monitoring visits, inspections and SIV’s
  - Challenge
    - Tight timelines
    - Changing CRO’s
- Receipt and administration of study documents, medication and devices

We lost a patient as we do not have the according DCB!
Tasks of a study nurse/coordinator

Study relevant procedures

- Taking patient history
- Blood sampling, handling and shipment of blood samples
- Study specific measurements
  - Duplex scan, hemodynamic parameters [ABI, TcPO2, Toe pressure, Walking test, Treadmill, Wound assessment, Physical exam, pulses, ECG, questionnaires,...]
- Randomization via IVRS [Assistance]
- Blinding/Unblinding of patients [Assistance]
Tasks of a study nurse/coordinator

Training

- Ongoing training
  - [Austria specific: Clinical trial specialist with update every year]
  - Update of GCP certificates
  - Participation in SIV’s, and investigator meetings, international meetings.
Tasks of a study nurse/coordinator

Miscellaneous

- Coordination of operational procedures between hospital, pharmaceutical companies, competent authorities, CRO’s and contract research institutes
- Support in cooperation between different departments within the hospital

And most important keeping the PI in good humor!
Tasks of a study nurse/coordinator

To summarize

- For a good functioning study site the study coordinator is the key person
- A lot of tasks and responsibilities, which are growing due to growing demands from regulators
- The study coordinator is the key contact person to the patient who is the key component of a trial

But you can have fun!
Tasks of a study nurse/coordinator
Tasks of a study nurse

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