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Working with Difficult Investigators

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Disclaimer: All names have been changed to protect the difficult.

Principal investigators are the heart of clinical research. Their dedication to finding cures gives them the right to be a bit difficult at times. (The investigators we know, of course, do not exercise that right.) Nevertheless, plenty of investigators have, shall we say, their eccentricities. We are, after all, people working with people, each with our own personalities, work styles, and motivations. That being said, there are effective ways to work with difficult investigators. But first, we have to recognize when we are, in fact, working with a difficult investigator and diagnose what type of difficult investigator we are dealing with. The following 11 types of difficult investigators are common:

Dr. Studies

AKA "Dr. We Can Do That"

Signs & Symptoms

- Wants to conduct every study that comes in.
- Takes the invitation to participate in a study as evidence that the site is qualified to conduct the study.
- Says: "We see those patients all the time."
- Sees problems with a study as obstacles to be overcome.
- Is convinced that friendly physicians will refer their patients (based on no prior evidence).
- Sees thorough feasibility analyses as "overkill."
- Believes that cleverness and hard work conquer all obstacles.
- Loses interest in old studies as new ones come in.

Prescription

- Develop guidelines for accepting studies.
- Select studies from groups of potential studies, e.g., the best of eight available.
- Implement a thorough feasibility analysis process.
- Keep a record of the site's success with studies in terms of enrollment and financial impact.
- In the decision process, involve the study coordinator who will be responsible for the cleverness and hard work.
- Tell the investigator: "Let's hope so. We'll know soon."

Dr. Enrollment

AKA "Dr. I Want to Enroll an Incarcerated Schizophrenic Patient with Dual Primaries"

Signs & Symptoms

- Wants to enroll *every* patient in some clinical trial.

- Insists the patient has only a "little bit" of dementia.
- Looks for ambiguities (i.e., loopholes) in the eligibility criteria.
- Describes eligibility criteria as guidelines.
- Gives ineligible patients the idea that they will be enrolled in the study.
- Is a "good friend" of the medical monitor, who "understands how these things work."
- Expresses frustration with "up-tight" study coordinators who "want the study to fail."
- Excitedly tells you about the "perfect subject," who has just a few minor issues like Hepatitis A, B and C, short-term memory loss, abnormal bleeding of the brain, shortness of breath, and occasional marijuana use.

Prescription

- Provide regulatory compliance training.
- Hold a conference call with the study sponsor to discuss the meaning of eligibility criteria.
- Enter accolades like "Good try!" on the accrual report, with explanation of why patient was not eligible (as a reminder to all).
- Schedule a heart-to-heart conversation for the investigator with the medical monitor.
- Tell the investigator: "Too bad about this one, but now we'll work even harder to find subjects for the study."

Dr. Yes

AKA "Dr. I'll Do It by the End of the Day"

Signs & Symptoms

- Answer to everything is "yes":
  - Can we really enroll 20 subjects? "Yes."
  - Can you attend the investigator meeting? "Yes."
  - Can you talk to Mrs. Smith about the study? "Yes."
  - Can you sign the lab reports today? "Yes."
  - Can you meet with the site monitor this afternoon? "Yes."
- Does not meet commitments.
- When pressed, says: "So you think we should just let the patients wait?"

Prescription

- Make it clear from the beginning that commitments must be met.
- Provide written reminders.
- Block out time in calendar for research activities.
- Review the IRB approval letter and clinical trial agreement with the investigator.
- Show the investigator the draft of a letter to the IRB requesting termination of the study because of lack of resources.
- Schedule a heart-to-heart conversation for the investigator with the study manager.
- Create a system of privileges and penalties, including loss of the right to conduct research.
- Provide periodic regulatory compliance training.
- Tell the investigator: "You are just too eager to please. There is only so much time in the day, so let's make the best possible use of it."

Dr. Busy

AKA "Dr. Can You Come Back Later?"

Signs & Symptoms

- Is always occupied or on the way to an important meeting or can't be interrupted.
- Often starts late and runs behind schedule for the entire day.
- Desk is often deep in paper.
- When running down the hall, says: "I'll be back in a minute."

Prescription

- Make requests as quick and easy as possible to fulfill.
- Schedule meetings in advance, preferably at the beginning of the day.
- Track metrics, e.g., number of days before lab reports get signed.
- Where appropriate, obtain delegations of authority.
- Recruit a sub-investigator.
- Reduce number of studies.
- Schedule a heart-to-heart conversation for the investigator with the study manager.
- Tell the investigator: "The rest of your day looks very busy, so please take care of this now."

Dr. Uninvolved

Dr. "If You Need Me, You Know Where to Find Me"

Signs & Symptoms

- Never takes the initiative, but is available for a talk.
- Will never seize responsibility but will accept it and then not follow through.
- Expects study personnel to "handle the details."
- Is surprised when goals are not met or problems occur.
- May display passive-aggressive behavior like casually suggesting that something should be done and then complaining when it does not happen.
- Says: "I don't know what we'd do without you."

Prescription

- Provide regulatory compliance training.
- Make investigator's responsibilities clear, e.g., with checklists.
- Schedule a heart-to-heart conversation for the investigator with the study manager.
- Tell the investigator: "I know you're busy, but the regulations are clear that you have to do this."

Dr. Intimidation

AKA: "If You Have to Ask, You Must Not Know What You Are Doing"

Signs & Symptoms

- Makes it clear that you are imposing on him or her by pausing and staring before reluctantly speaking with great authority.

- Threatens to speak to your supervisor, the study manager, or the medical monitor.
- Grumbles about the sad state of affairs.
- Says: "As you should know,…"

Prescription

- Do your homework.
- Minimize interactions with the investigator, e.g., by communicating in writing.
- Tell yourself that it's him or her, not you.
- Tell the investigator: "I should probably know this, but…"

Dr. Condescending

AKA "Dr. I'm the Doctor Here"

Signs & Symptoms

- Displays lack of interest in study coordinator's views on eligibility and adverse events.
- Takes IRB suggestions as expressions of ignorance.
- Insists that all study coordinators be registered nurses.
- Uses phrases like, "As a physician," "Since you are not a physician, you can't be expected to understand," and "If you knew anything about the disease process, you would know this patient meets the criteria."

Prescription

- Conduct a conference call with the study sponsor, preferably the medical monitor, to discuss roles and responsibilities.
- Request medical monitor review of de-identified source documentation for eligibility.
- Study the protocol and investigator's brochure and then discuss some obscure points with the investigator.
- Tell the investigator: "Of course, I'm not a physician, but…" or "Unfortunately, we have to follow the protocol as written," or "Would you like me to get clarification from the medical monitor on this point?"

Dr. My Rules

AKA "Dr. Rules Are for People Who Need Rules to Follow"

Signs & Symptoms

- Acts unpredictably in ways that make sense to some extent but create extra work for others and may not comply with the regulations.
- Tries to circumvent the randomization and blinding process.
- Training does not seem to sink in.
- Says, "We have a job to do and it's not filling out a lot of paperwork."

Prescription

- Provide periodic regulatory compliance training, focusing on consequences of broken rules.

- Watch for rule violations. Correct the resulting problems as quickly as possible. Record the violations and their consequences.
- Create incentives for following the rules and disincentives for not following them. For example, Corrective and Preventative Action (CAPA) plans can be more work than just doing things correctly.
- Ask others to tolerate investigator's eccentricities.
- Tell the investigator: "I know the rules can seem silly, but it will save us both a lot of time and aggravation if we follow them."

Dr. Compassion

AKA "Dr. Let's Find a Way to Treat this Patient with the Study Drug"

Signs & Symptoms

- Sees clinical research as a form of medical treatment, not as scientific experiment.
- Asks to open trials for only one patient, who "really needs the drug."
- Estimates high accrual goals on the assumption that a way will be found to enroll patients who need the study drug.
- Hands patient chart to the study coordinator and asks for a list of clinicaltrials.gov trials (that probably have already lined up their sites).
- At the end of a study, explains to the study coordinator that missing study drug has been dispensed to a patient who cannot afford treatment.
- Wants to start three compassionate trials immediately.
- Says: "Don't worry; we'll find a way."

Prescription

- Provide regulatory compliance training.
- If necessary, create standard operating policies and procedures.
- Develop and adhere to study feasibility process.
- Measure the cost of conducting trials with minimal enrollment.
- Tell the investigator: "For now, let's try to enroll lots of qualified patients in the studies we have. That will give us more flexibility later."

Dr. Money

AKA "Dr. What Does the Study Pay?"

Signs & Symptoms

- First question about a study is, "What does it pay?"
- Focuses on how to enroll subjects and keep them in the study.
- Is not very interested in study details other than the budget worksheet.
- Presses study coordinators to increase billable activities.
- Ignores studies that are not paying off.
- Says: "You know, we're not running a charity here."

Prescription

- Implement a thorough feasibility analysis process.

- Ensure that investigator does not pressure subjects into enrolling in or staying in studies.
- Tell the investigator: "We can maximize profits from this study by minimizing distractions like enrolling subjects that just drop out."

Dr. Publication

AKA "Dr. I'm Giving Five Talks at ASCO Next Month"

Signs & Symptoms

- Insists on being listed in jointly authored papers, regardless of subject enrollment.
- Criticizes industry studies as evidence of more funding than good sense.
- Describes IRB submissions as bureaucratic paperwork.
- Strongly encourages patients to enroll in studies.
- Asks research staff to prepare emergency grant submissions for "important" research projects.
- Instructs the study coordinator to obtain IRB approval of a new study by tomorrow so the investigator can present it at a conference next week.
- Knows exactly how many papers are listed in his or her C.V.
- Is still angry about being listed as third author on a paper published last year.
- Says: "Why *shouldn't* I be an author?"

Prescription

- Create a Trial Request Form and IRB Submission Form that clearly state timeline requirements.
- Invite a representative from the local IRB to give a presentation on the study review process, requirements and timelines.
- Tell the investigator: "I am so proud to have been part of so many publications. Let's make sure we do this one right."

Conclusion

Given the challenges, it is admirable for any physician to take on clinical research responsibilities. The key point to remember is that an investigator's difficult traits might be hiding a truly wonderful investigator. By tailoring our behavior to their quirks, we can often help investigators shed their difficulties or at least make them manageable. At the end of the day, we can leave work knowing that their dedication to research could ultimately prolong our lives. Also, when investigators go home and sit at the dinner table with their families, they probably say, "You would not believe what my study coordinator did today — she can be so difficult!"

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