To the Quantum World reprint article

Here is an article from the FDA wanting you the therapists to do clinical research. If you have an idea of what your SCIO has done to help your patients here is your chance to prove it to the world. You can write up a case study on a patient and submit it to us for publication. You might get approved to present it at our world congress in Budapest. But if you want to do a proper study here is your chance.

The FDA is helping people to do investigator Sponsored Trials, known as IST. The following article is from an FDA approved journal on compliance. We have the proper Institutional Review Board, we have a study protocol for you to work with or amend for your needs, and we have the medical supervision. We have all you need. You just need an idea, some patients, and the dedication to see it thru. If you can finish a full 20 patient abi blind study you can get a refurbished SCIO from the sponsor Maitreya / SCIO USA. So think this is your chance to get your name on a study and show the world what you are doing. We can do it together.

Prof. Desiré Dubounet
Investigator-sponsored Trials

Thousands of clinical trials are conducted each year around the world. They are sponsored or funded by a variety of organizations such as medical institutions, foundations, voluntary groups and pharmaceutical companies, in addition to federal agencies such as the National Institutes of Health and the Departments of Defense and Veterans Affairs. In addition, some clinical trials, sponsored by individual physicians, are called investigator-sponsored trials (ISTs).

ISTs are like other clinical trials, except that they are mostly single-center studies with an individual physician acting as both the lead investigator and the sponsor. As a result, ISTs tend to be minimally funded. However, if the drug or medical device under investigation in the trial is already available commercially (perhaps for another indication or population), the investigator will often try to engage the manufacturer to obtain some form of funding (e.g., donating the drug or medical device). Data generated through ISTs are often published and contribute significantly to academic research that in turn is referenced and utilized by other treating physicians and entities involved in the disease area or condition. Ownership of the products being investigated in the ISTs remains with the patent holder or manufacturer. Therefore, if the investigator is not the patent holder, he may neither submit the data from ISTs to a regulatory authority nor obtain approval to market the product. The investigator will need to work with the patent holder to obtain the rights to the product and it may be necessary to license the product to a manufacturer to secure the funding needed for the resources required for product approval. Data from ISTs are accepted by many regulatory authorities to support marketing applications or supplements as long as the trials were conducted in strict conformance Good Clinical Practice guidelines and the regulatory authority has access to uninterpreted data from the trial.

ISTs are held to the same regulatory standards as all trials involving human subjects. Investigators who sponsor and/or participate in clinical trials have serious responsibilities because of the involvement of human subjects and their risks in participating. There are many regulations specifying the responsibilities of sponsors and investigators. Investigators who are both sponsors and investigators (investigator-sponsors) of clinical trials must shoulder both sets of responsibilities and become very familiar with all applicable laws and regulations surrounding the conduct of human studies to ensure compliance. In the US, the Code of Federal Regulations (21 CFR Part 312 Subpart D for drugs and biologics and Part 812 Subparts C and E for medical devices) describes these serious responsibilities for both the sponsor (21 CFR 312.50) and the investigator (21 CFR 312.60). Additional responsibilities and requirements are described throughout 21 CFR 312 and 812;

those specifically relating to informed consent and IRB approval are described in 21 CFR Parts 50 (Protection of Human Subjects) and 56 (IRBs), respectively. The specific responsibilities for sponsors and investigators in drug and biologic clinical trials are similar but not identical to those for sponsors and investigators in trials for medical devices.

Investigator-sponsors must determine whether an Investigational New Drug application (IND or Investigator IND) must be submitted to the US Food and Drug Administration (FDA) before beginning the trial. An IND is usually required if the study involves an unapproved product or an approved product for a new indication, or evaluation of an approved product in a new patient population. The IND must include all
the information specified in 21 CFR 312.23. To complete the IND, the investigator-sponsor usually seeks permission from the original product manufacturer to cross-reference the company's IND or Investigational Device Exemption, or approved New Drug Application or Premarket Application to obtain the necessary information (e.g., data from animal studies and previous human studies and manufacturing information). By submitting an IND, the investigator assumes responsibility for providing all necessary information (such as the study protocol, adverse event information, annual reports, etc..) to FDA to maintain compliance with regulations. It remains the investigator's responsibility to determine whether the study is exempt from the requirement to submit an IND. FDA generally does not accept INDs it considers exempt (see 21 CFR 312.2(b)(1) for criteria that exempt studies from IND regulations).

Table 1 lists some common reasons why investigators sponsor clinical trials in spite of the tremendous regulatory burden such studies entail. A key challenge investigator-sponsors face is the large amount of time they must dedicate to the study and how that impacts caring for patients in their medical practices. The investigator-sponsor must supervise the trial, interact with the IRB, develop budgets, deal with audits and inspections and travel as needed. Well-qualified, experienced, trained and efficient personnel (in particular the study coordinator, but also including the sub-investigators, research nurses and laboratory personnel) become essential to the investigator in managing the trial workload.

Investigator-sponsors who take the time at the beginning of the trial to train any noncertified personnel in the International Conference On Harmonization (ICH) guideline, Good Clinical Practice E6(R1) will generally save time on the back end and improve the quality of the study.

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<tr>
<th>Table 1. Advantages for Investigators In Sponsoring Clinical Studies</th>
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<td>1. Patient care: Investigators can more rapidly offer their patients unapproved but promising products or</td>
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<td>2. Scientific collaboration: ISTs allow Investigators to remain at the cutting edge of their therapeutic interests.</td>
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<td>3. Scientific contribution: When Investigators publish the results of their studies, they enable manufacturers to</td>
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<td>4. Professional recognition: Publications provide the Investigator with professional recognition as an expert or thought leader in the field. There is value in publishing even those studies that did not meet their primary hypotheses.</td>
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<td>5. Funding: As the Investigator becomes well-known in the field, he is able to secure funding more easily, thereby furthering future research.</td>
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**What's in It for the Patient?**

ISTs are a very good option for patients to obtain access to new and as yet unapproved research therapies. People often participate in ISTs because they have exhausted approved treatment options that either did not work for them or produced intolerable side effects. Carefully conducted ISTs are a relatively safe and quick way to get access to products that have the potential to treat the disease or condition or that have the potential to improve patient health or quality of life. Further, since investigators are often specialists in the disease area being studied, some patients participate to gain access to expert medical care for their condition, thereby playing a more active role in their own healthcare. Still others participate in ISTs for the purely altruistic reason of wanting to contribute to the advancement of medical knowledge.

Not all patients who apply to participate in an IST will be accepted. Each patient must meet predetermined eligibility criteria, such as age, sex, type and stage of disease, previous treatment history and other medical conditions. These criteria help to reduce the amount of variation and “noise” in the study, without threatening the scientific integrity of the trial, by removing medical variations that might complicate data analyses and the ability to draw relevant and sound conclusions. Patients may also be excluded because the researcher has already enrolled the required number of participants needed to test the hypothesis stated in the study protocol.

Once subjects are selected to participate in the IST, the law requires the investigator to obtain informed consent. The investigator must provide patients with complete and accurate information about what will happen during the trial and disclose all known or suspected risks. Participants must sign a written informed consent form, which indicates they understand the trial is a research study, have been informed about the associated risks and are aware that their participation is voluntary and they can leave the clinical trial at any time. Additionally, the consent form should outline in detail the amount of time participants will have to devote to the trial and the types of activities; for example, they may need to visit the study site at specified intervals, be subjected to additional tests, get more treatments than are normally necessary, stay in the hospital and/or follow complex dosage requirements. Patients use the material in the informed consent document to decide whether or not to enter a clinical trial and to make an informed decision about the level of risk they are willing to accept before they enter the trial.

The investigator should clearly explain to participants (when applicable) that they may not receive the investigational drug and may instead receive a placebo. They should also be prepared mentally for partial or no effectiveness from the treatment. The investigators should encourage the participants to learn as much as possible about the clinical trial and the investigational treatment and to freely discuss their questions and concerns with members of the research team.

**Registration of Clinical Trials**

Investigators and sponsors usually register their trials with databases such as http://clinicaltrials.gov/, an interactive online database managed by the National Library of Medicine. Clinicaltrials.gov facilitates the registration of trials in accordance with the International Committee of Medical Journal Editors (ICMJE) initiative requiring prior entry of clinical trials in a public registry as a condition for publication. Members of the public can find information about clinical trials by searching http://clinicaltrials.gov/ as it lists both federally and privately supported clinical
research. The site, which is updated regularly, offers information on the objectives of each trial, eligibility criteria, locations and contact details to obtain more information.

Summary

For patients, ISTs are a viable option for obtaining access to unapproved treatments. For physicians acting as investigator-sponsors, ISTs offer key benefits such as professional recognition and the opportunity to continue participating and collaborating in cutting-edge scientific investigations (see Table 1). However, ISTs present challenges to both investigators and patients. To be successful, investigators and investigator-sponsors must be highly motivated leaders with the skills and drive to coordinate the activities of many people to ensure completion of all study activities. Success generally requires careful planning, evaluation and management of the multiple aspects of conducting a clinical trial in accordance with all applicable regulations and ensuring that the various pieces of the puzzle fall into place seamlessly.

While ISTs provide patients with accelerated access to new treatments, these treatments have not received thorough review by a regulatory agency such as FDA or the European Medicines Agency, and as such, risks and uncertainties are unavoidable. Volunteers need to ask relevant questions of the researchers, remain vigilant for changes in their health status (particularly adverse changes), report them immediately and, in general, be aware that they shoulder significant responsibility as participants in an IST.

References

- Good Clinical Practice: Consolidated Guideline E6(R1), ICH (June 1996).

Author

Naseem Kabir, MS, RAC, is director, regulatory affairs international, at Genzyme Corporation, based in Cambridge, MA. She has been in the pharmaceutical and medical device industries for 20 years and in regulatory affairs for the last 12 years. Kabir holds a master of science in zoology from the University of Chennai, India and is RAC-certified in both the US and EU. She is a member of the Board of Editors for RAPS’ Regulatory Focus magazine and can be reached at naseem.kabir@genzyme.com.
The FDA is now encouraging all people using devices to do studies to validate and verify device claims, while perhaps uncovering new ways to help people. We have an Institutional Review Board for America all is set to allow you to do studies and get your name onto a medical research paper. We are the sponsor and our medical doctor team will help your study and assist you.

To start this first enroll onto the research team by going to the qxsubspace.com website and filling in the research team application. This work can be used as part or all of your doctoral or diplomat thesis.

Then give us an idea of what you can do a study on. You will need to make a basic premise that you and your therapy can help people with a problem. It is a good idea to review the style of our studies by going to the IJMSH at [http://ijmshem.com/](http://ijmshem.com/).

You will have to familiarize yourself with the informed consent process. All subjects must give informed consent to participate there are 8 elements of informed consent. They can sign a form or give verbal consent to participate. You can charge them if you wish, it is up to you.

If you do the work we can help you publish. You need to make a pretest of something like how long can you hold your breath. Measure how long your subjects hold their breath, do the 45 min to 1 hour therapy (any therapy in the SCIO/Indigo you wish) then re-measure, asking them to hold their breath.

Pre-test, then Therapy intervention, then Posttest. Collect and send the data, Easy.

Record their personal data and SOC data and the Pretest, What therapies you did, Posttest and send them to us. Do not send us the names of the subjects, this is confidential. You should do 10 subjects as a minimum and we will credit you $100 off of your activation screens for each ten you do.

If you do a case study paper on two subjects with a thorough analysis we will also credit you.

We will help you with professional references and study format. It is basically abstract summary, intro of hypothesis, method of testing, data presentation, conclusions, discussions opinions, and references. We can help with these. And we can get them published in a professional recognized peer reviewed medical journal.

Ideas you might want to measure is pain sensation, flexibility, strength, memory, etc. we recommend using verbal reports of feeling but not just verbal reports. The verbal mind can be fooled.
If you want to go all the way and do placebo testing where during some of the tests, we can do that from here by resting your computer to placebo from here. This makes the system appear to do all functions while actually being off. Then neither the therapist nor the subjects know when the therapy is real. If we show that suggestion and placebo effect are not responsible for the effect we get a very good study. But this is for the more professional.

So don’t be afraid, don’t worry, don’t judge, be happy and help the world as we further validate and verify what we do.

Desire’ Dubounet
Thank you for participating in our research!
Please fill in the following agreement and send it signed and dated to Desire’ Dubounet at desire.dubounet@gmail.com or Andreea Taflan at andreea@qxsubspace.com.
Investigator Agreement

The Investigator below agrees to perform the study sponsored by Mandelay Kft. “A double-blind placebo-controlled study of the application of the SCIO Universal Electrophysiological Biofeedback System for statistical evaluation of the SCIO’s ability to increase Body Wellness after one 45-minute session” under his responsibility according to this definitive study plan number, CT-102-02, and in accordance with GCP regulations (Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance) and with MEDDEV 2.7/4 December 2010 (Guidelines on Clinical Investigation: A Guide for Manufacturers and Notified Bodies).

Name of Investigator

______________________________

Signature

______________________________

Date

______________________________
INFORMED CONSENT TO PARTICIPATE IN MEDICAL RESEARCH

PROJECT TITLE: A double-blind placebo-controlled study of the application of the SCIO Universal Electrophysiological Biofeedback System for statistical evaluation of the SCIO’s ability to increase Body Wellness after one 45-minute session

PRINCIPAL INVESTIGATOR:

SPONSOR: Mandelay Kft.
INSTITUTIONAL REVIEW BOARD: feki (freiburger ethik kommission)

1. The SCIO system research is to study millions of people with a wide variety of diseases to see who improves wellness.
2. It is our theory that the SCIO device can improve body wellness and the body electric factors by measurable amounts in one session.
3. The device and the study are always voluntary, confidential and safe.
4. There are a wide amount of benefits to wellness already displayed by the thousands of users and millions of patients. A millions of people have already been helped.
5. Results of the study and answers to your questions are available.

<table>
<thead>
<tr>
<th>Subject Consent</th>
<th>Person obtaining consent</th>
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<tr>
<td>I have read this form and have had an opportunity and time to ask questions. All of my questions have been answered to my satisfaction. I am giving my informed consent to take part in the study. I may be given a signed copy of this consent form for my records if I request it.</td>
<td>I have discussed this form with the subject. An explanation of the research was given and questions from the subject were solicited and answered to the subject’s satisfaction. In my judgment, the subject has demonstrated comprehension of the information.</td>
</tr>
<tr>
<td>I declare that I give my consent to the recording of my medical data within the framework of the clinical investigation and I agree that representatives of the client or of the appropriate authority can look at the data for investigational purposes.</td>
<td></td>
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Signature

Printed name

Date and Time