



Society for Clinical Trials

SCT President **Professor Dan Sargent** speaks of the importance of maintaining transparency and rigour, the Society's role in marrying different sectors through mutual scientific goals and the exciting developments that are advancing innovation in clinical trials

Could you give an insight into the central ethos of the Society for Clinical Trials (SCT) and its members?

SCT is an international, professional organisation dedicated to the theory and practice of clinical trials. The Society is a unique group with representatives from government, academia, industry, for-profit and non-profit sectors. We differ from groups specialising in one discipline, disease or therapeutic area because we recognise the need for understanding and communication at all levels. SCT is multi-speciality, with contingencies of members in disciplines of medicine, statistics, data management, IT and trial administration. What we share is a common desire to learn, while advancing the field of clinical research.

How do you combine the interests of the not-for-profit and for-profit organisations which are a part of the Society? Do you have common goals?

Within SCT, we are highly focused on the science and methodology of planning, conducting and reporting clinical trials. These are goals shared by industry, academia and government. Our board of directors, committee chairs and membership represent a very healthy mix of all three of these sectors. Improvements in clinical trial conduct to provide answers more accurately, quickly or at reduced cost are in all of our interests.

The Annual Meeting is the perfect opportunity for your members to come together to discuss topical issues. Could you illuminate the most talked about topics this year?

SCT Annual Meetings typically attract approximately 600 attendees representing our diverse membership. The two and a half day event features half- or full-day pre-conference educational workshops, plenary and concurrent invited sessions, contributed paper oral sessions and poster presentations.

This year's presidential invited speaker sessions, for which audio and video recordings are available to SCT members via the SCT website (www.sctweb.org), featured talks on the massive amounts of data that are now being generated in biomedical science and the implications for future research. The second plenary session provided an overview of the challenges associated with research on substance addiction and required levels of evidence. Other hot topics during the meeting were adaptive clinical trials, data sharing, recruitment strategies, the use of social media in clinical trials and risk-based monitoring of ongoing trials.

With a diverse membership that includes key decision makers and stakeholders, SCT is well-placed to influence policy. Is this an important part of your remit and could you provide a recent example in which you had an influence on a policy decision?

Expanding SCT's role in policy debates is an essential component of our strategic plan. We pursue this through multiple avenues, including the provision of position papers on timely topics, special topic invited sessions at our Annual Meetings and discussions with regulatory or other bodies regarding issues that are important to our membership.

A recent example is the SCT signing of a petition in support of the AllTrials initiative (www.alltrials.net), with a signing statement as follows:

"Transparency of clinical trial study design and results is important to researchers, physicians and the public. In order to design the highest quality and most ethical clinical trials in the future, we need to learn from and incorporate all past experience. The Society for Clinical Trials has signed this petition because each study participant deserves to have the data he or she contributed yield the maximum benefit to society."

The Rapid Anticonvulsant Medication Prior to Arrival Trial (RAMPART) was named Trial of the Year by SCT. For what reasons did this research receive such an accolade?

Each year, SCT presents an award to the randomised clinical trial published in the previous year that best fulfils the following standards:

- It improves quality of life of humankind
- It provides the basis for a substantial, beneficial change in healthcare
- It reflects expertise in subject matter, excellence in methodology and concern for study participants
- It overcomes obstacles in implementation
- The presentation of its design, execution and results is a model of clarity and intellectual soundness

SCT formally recognised RAMPART as the 2012 Trial of the Year at the May 2013 meeting. Published in the *New England Journal of Medicine*, the study was conducted in children and adults using the emergency medical services system and a consent exception. As a result, emergency medical technicians have a quicker and more practical way of treating life-threatening seizure conditions even before patients reach the hospital.

With current medical training being predominantly funded by medical students in the US, how can graduates be persuaded to stay in research which may be less well paid than other opportunities?

Each person has their own motivations. In medicine, it is indeed true that pursuing a research career may result in reduced financial reward. However, there are other rewards from research which are very attractive to some. Research is very challenging, and you can go for years without any major breakthroughs, but I find it highly rewarding to be working to develop better therapies for patients – extending and improving their quality of life.

Participation in research also opens doors in terms of involvement in and recognition from professional societies, the ability to 'protect' your time to focus on what is of greatest interest to you, and the potential for deep, long-term collaborations with other researchers around the world.

Bench-to-bedside medicine must be conducted at a pace so that innovative therapies are rigorously tested but reach patients in a timely manner. Is the current process optimal or could improvements be made?

Data from rigorously conducted clinical trials have long been viewed as the gold standard for the evaluation of medical interventions. Fundamental to the progress of clinical medicine has been the concept of randomisation between interventions, which is the most important tool we have to reduce bias. As with any methodology, however, many challenges continue to be pursued by the Society and its members. These include the vastly expensive and tedious work of extensive on-site source data verification which is the standard for many industry-sponsored trials.

Patient consent forms, which are an essential component of ensuring patient involvement, safety and commitment, have become extremely long (often >20 pages) and the question of who are we protecting – the patient or the sponsor – is on many of our minds. The vast amount of redundant reporting required for clinical trials – the trial sponsor, independent data safety monitoring boards, local institutional review boards and the US Food and Drug Administration – places a heavy burden on the triallist.

Excessive data collection is rampant – a recent study published in the SCT's journal *Clinical Trials* indicated that on average only 18 per cent of data collected on study case report forms are reported on in manuscripts. These and many other issues form the basis of much of the work of the Society – how can we maintain the very substantial strengths of clinical trials while improving efficiency, maintaining trial participant safety, and reducing both trial participant and researcher burden?

What advice would you give to a person who has been invited to take part in a clinical trial?

Regardless of the condition, I would strongly recommend that any individual considers participating in a clinical trial. While being in a trial may not directly benefit the trial participant, the information from trials helps future patients with the disease or condition under study.

Randomisation should not be feared – trials undergo extensive review to ensure that the current standards of care are present in the control arm, and trials are monitored tightly to ensure patient safety and the potential for early superiority of one intervention over another.

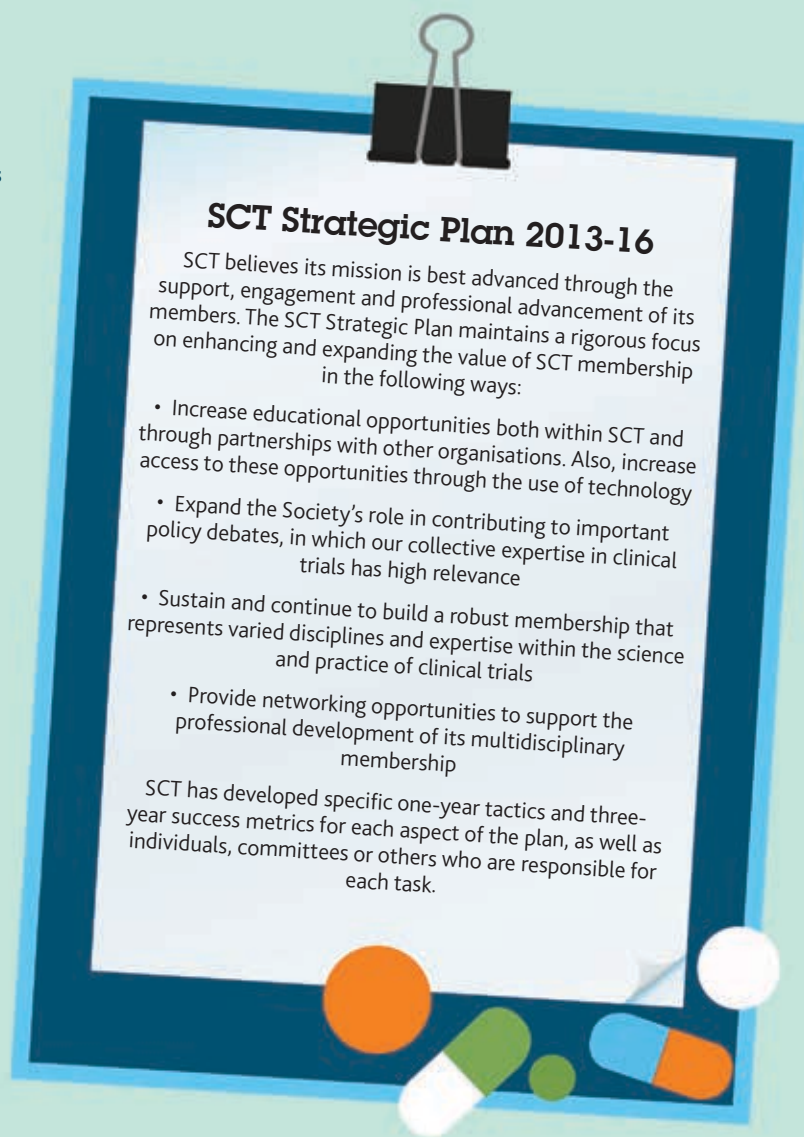
However, it is critical that the potential participant fully understands the nature of the trial, what other options may be available for treatment, what (if any) costs might be incurred by the participant and, importantly, what side-effects or adverse reactions might be possible. Clearly the best advice is to ask many, detailed questions.

Could you describe the purpose of the Thomas C Chalmers Student Scholarship?

The Scholarship honours this champion of clinical trials by encouraging students to attend the Society's Annual Meeting and take the opportunity to network with clinical triallists from around the globe. SCT initiated the programme in 1985. Entries may relate to any clinical trial-related issues, such as study design and data analysis methods; meta-analysis; medical, ethical or legal issues; data entry, management and computing related to clinical trials; review of the results or methods of a class of trials; or scholarship in the history of clinical trials.

Overall, which aspects within the arena of clinical trials have you been most enthused about this year?

Rather than any individual trial, I have been most enthused this year by the continual innovation we see in the field of clinical trials. The discipline



is being challenged, in a very healthy way, by rapid advances in medical knowledge. We are facing an abundance of new agents to test, some with remarkable efficacy, in a very resource-constrained environment.

Electronic, sometimes automated, data collection is allowing us to monitor and potentially adapt trials based on new or emerging information as they progress – this is very exciting but it also must be considered very carefully. I am also very excited about direct, real-time data collection from patients to the triallists through electronic tools such as smartphones and other devices. These devices may enhance access to clinical trial participation and allow larger, simpler trial designs.

www.sctweb.org

