THE EVIDENCE MULTIPLIER

Using insight from patients' experiences of clinical trials to drive future success

alterline

THE EVIDENCE MULTIPLIER: IN BRIEF

The experience of participating in clinical trials has a huge impact on the reputation of trial organisers and funders, and on the success of future recruitment - yet its importance is often ignored.

Good experiences include those where participants 'feel better' - due to the physical effects of the intervention itself, or the psychological effects of monitoring and self-evaluation.

Information must be accessible, consistent and clear to ensure patients fully understand the procedures of the trial and what it requires of them.

A trial must fit into patients' everyday lives, and and accommodate their responsibilities outside of the trial, to dependents, partners and employers.

Front-line staff at trial centres are integral to the building of good relationships and making participants feel valued.

An evidence multiplier is created by augmenting clinical evidence with psycho-social data on human experience, increasing the power and cost-effectiveness of clinical research.

MISSING DATA:
THE HUMAN EXPERIENCE

The enormous variation in the personal, human experience of participants has received scant attention within clinical research, perhaps in part because the formal procedures by which clinical trials are conducted are subject to such heavy regulation. This is surely a significant blind spot in a field so dependent on the behaviour of human subjects for it to remain clinically and commercially viable.

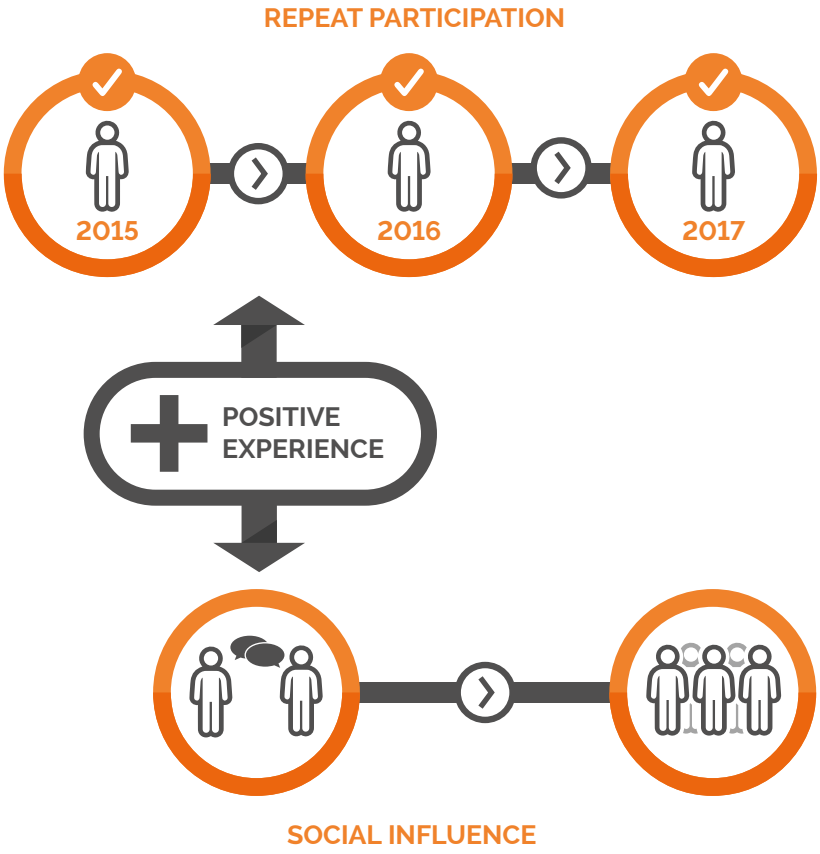
So what does the existing evidence base show about the significance of the experiential dimension of the participation in clinical research? And what areas of practice demand further attention to keep organisations who conduct clinical research pushing towards the cutting edge and meeting the challenges of health and wellbeing in the 21st century?

BACKGROUND

Clinical research can be both time-consuming and expensive, with some $10 billion dollars spent on clinical trials by biopharmaceutical companies in the United States in 2013 alone[1].

For many patients, their involvement in a trial will be their first direct contact with the organisation running it; for the organisation, making a good impression is therefore critical to their reputation in the market and subsequent sales. Despite this, research into the experience of taking part in clinical trials is limited and many of the existing studies in this area focus on the motivations of individuals for participation, rather than exploring their experience once they have agreed to be involved. The emphasis on this area is understandable, given how critical recruitment is to success or failure of trials in the short-term. The findings indicate consistent patterns of repeat participation and social influence effects in recruitment – those who have participated previously are likely to participate again, and being personally acquainted with someone who has been a participant increases the likelihood that an individual with no prior trial experience will sign up[2]. What connects these two tendencies is the defining role of the individual's experience of the trial: those who have had good experiences are more likely to take part again; they are also more likely tell others about their experience.

THE MEDIATING ROLE OF POSITIVE TRIAL EXPERIENCE IN TRIAL RECRUITMENT



KEY CONSIDERATIONS

UNDERSTANDING WHAT PEOPLE HOPE TO GAIN FROM PARTICIPATION

It is clear that understanding what makes a good experience is important, however unpicking this can be difficult, particularly for trials related to long-term health conditions. The very possibility that taking part might ameliorate a person's condition may make participation a positive experience for that individual, by offering hope for a treatment or cure however uncertain it may be.

However, since trials are by their very nature experimental, funders and organisers cannot rely on the premise that participation will result in "feeling better" as the main driver of positive experiences of participation – the possibility of allocation to placebo group, or entering a trial as a healthy participant underlines that fact.

Furthermore, in some cases trial co-ordinators have no prior knowledge of the desired result for patients. For example, in a trial comparing two treatments for atherosclerosis of the leg vessels, one treatment reduced blood pressure in the ankles, but did not reduce the pain of walking, whilst the other reduced the pain of walking, but did not improve blood pressure. How does one decide which is the mostimportant outcome – and which is more relevant to patients' rating of their experience as a worthwhile endeavour[3]?

It is also important to recognise the broad basis of the phenomenon of "feeling better" insofar as it encompasses psycho-social, as well as bio-medical, factors. Giving participants the opportunity to self-assess their emotional and physical state during the process can, in and of itself, be a source of satisfaction with the process[4]. This means that some aspects of the experience of wellbeing, or "being more well", which those with specific medical diagnoses hope for, may also be attainable by healthy participants, in addition to more generic benefits, such as the "warm glow"[5] of altruistic giving to good causes.

THE PLACE OF THE PARTICIPANT IN PROTOCOLS AND PROCEDURES

Often protocols for trials concentrate on the medical information and procedures which need to be followed by those conducting the trial. Yet these often omit to address the personal journeys participants undergo during trials, and the difficulties they may face in navigating this unfamiliar landscape.

The information provided to participants during a trial can make a crucial difference in this regard, however these materials are often written or presented in ways that are inaccessible to the layperson, or branded inconsistently with the key messages the organisation intended to communicate. Indeed, in one recent study into breast cancer treatment, participants were unsure of the scheduled end date for the trial, or of the process of coming to the end of the trial, and whether they would continue on the treatment – despite this being part of the information provided at trial commencement[6]. Such a lack of clarity around procedures and expectations can be extremely distressing for participants, whose involvement may require a significant donation of time and emotional commitment.

Beyond information, protocols often fail to take account of the fact that a trial participant has multiple responsibilities - they may be a parent, partner, employee and friend, as well as a patient.. Centres which open only during business hours or are located, in some cases, hundreds of miles from where a participant lives, can cause an inconvenience so great it negatively impacts on adherence and attrition. Ensuring the process is smooth can undoubtedly be difficult, however, fitting a trial around a patient's life is integral. Being obliged to sit alone in a bare room for hours without WiFi, or missing your child's school pickup because an appointment overruns, are not recipes for happy trial participation.

BUILDING RELATIONSHIPS DURING THE PROCESS

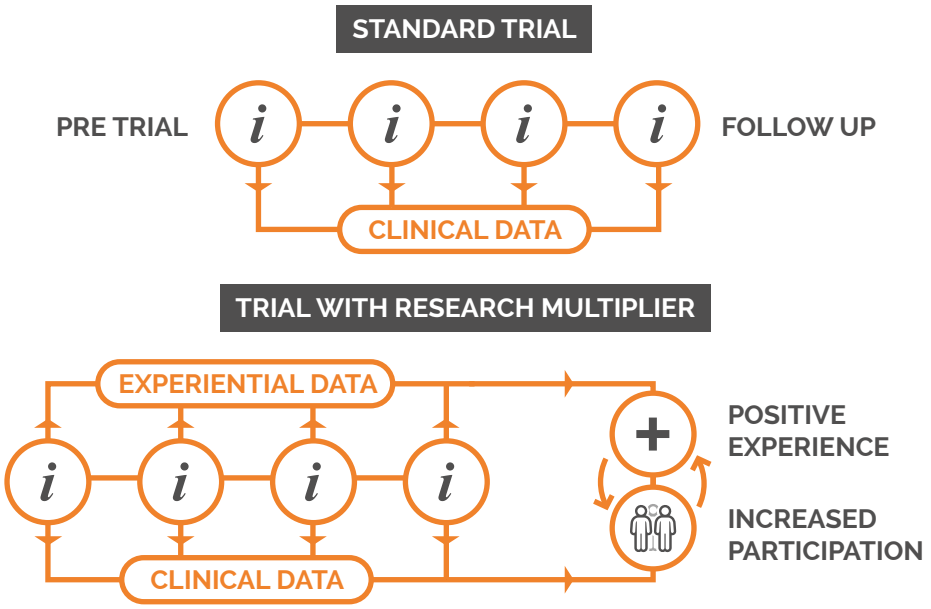
The provision of accessible and timely information is the foundation stone of a good relationship with trial participants, and as the first port of call for guidance and questions during a trial, the performance of front-line staff is crucial. If participants bring concerns about side-effects during trials and do not get satisfactory responses, or indeed any response at all, this can cause participants to feel frustrated with their experience of the trial and doubt the extent to which their contribution is valued[7].

Conversely, regular contact with friendly, professional, supportive staff, can significantly reduce attrition, by keeping participants in touch with the purpose of the study and the contribution it will make to medical knowledge, so that their effort and commitment feels worthwhile[8].

THE EVIDENCE MULTIPLIER: TRANSLATING EXPERIENCE INTO BETTER CLINICAL RESEARCH

The issues and activities outlined above illustrate the range of areas where research into patient experiences can make a difference and the opportunity this presents for organisations involved. At a time when more and more is being spent on clinical research by private organisations, charities and public bodies, it is clear that much more can be done to increase the levels of engagement and participation in clinical research by exploring the human experience of trial participation. Independent researchers with expertise in patient and participant experience of trials can interface with the protocol and process, across the patient journey (see diagram opposite), gathering intelligence that maximises the knowledge outputs and benefits to the organisation across all dimensions of the trial. This creates a multiplier potential, whereby both clinical and organisational learning can emerge, that may then be used to increase the power and cost-effectiveness of subsequent trials and build a more meaningful relationship between the public and clinical research community into the future.

THE PATIENT JOURNEY THROUGH THE STANDARD TRIAL AND TRIAL WITH EVIDENCE MULTIPLIER



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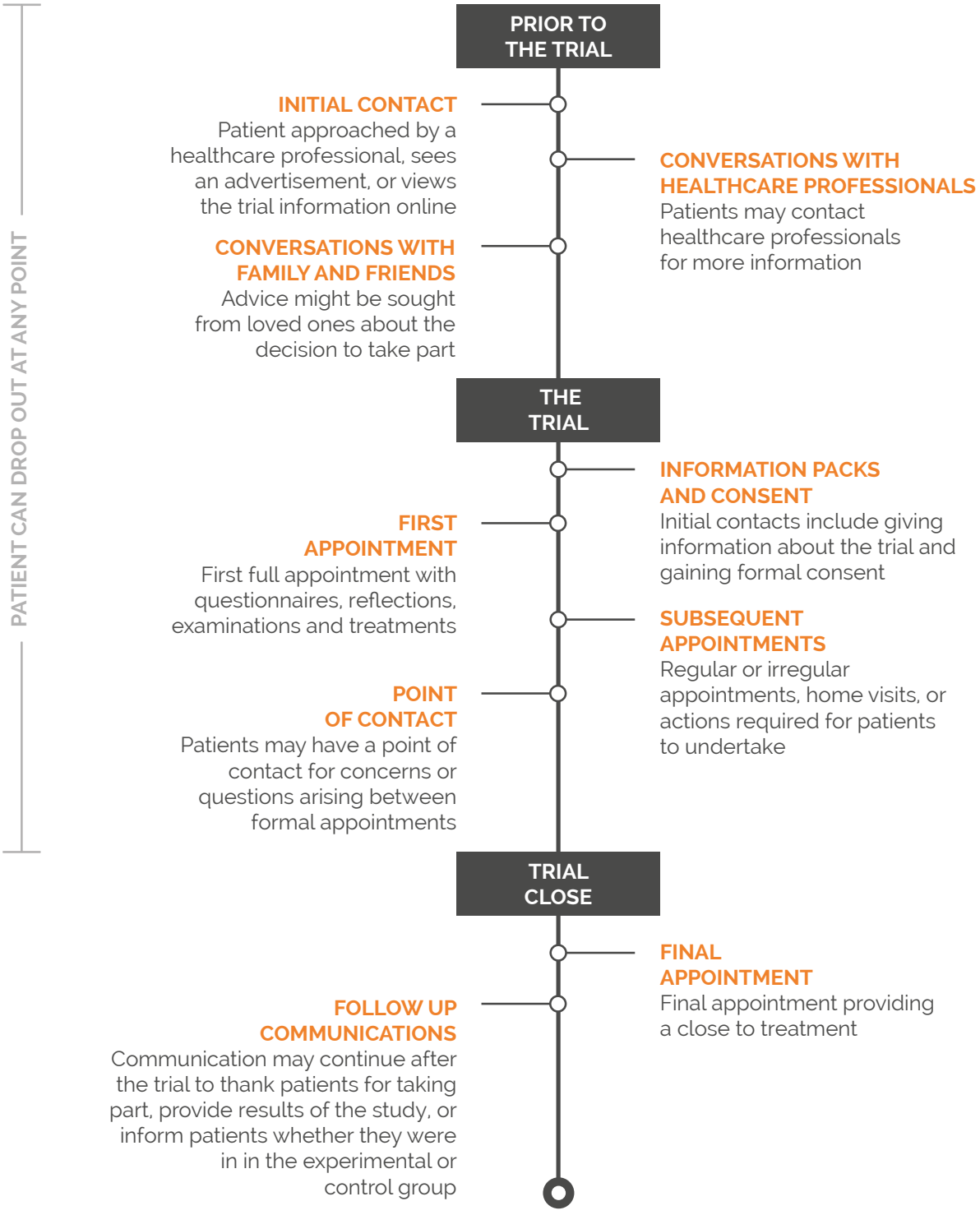
PATIENT JOURNEY

The research multiplier addresses itself to the details of the patient journey. By examining the key touchpoints along the path through clinical trials, we can produce an in-depth analysis of how patients, as people, navigate this unfamiliar landscape, and translate this learning into better clinical research.



WHO ARE ALTERLINE?

We are a strategic research consultancy specialising in health. We help our clients to understand patients' lives and experiences, connect to the needs of their audience, and use evidence to drive positive change.

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