

**Louvain School of Management**

# **Marketing in Clinical Trials**

**Advertising for Patient Recruitment and Retention**

**Final Dissertation**

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**Master in Management – GEHD2M1**

**Academic year 2019-2020**

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**June 2020**

## **Résumé**

Le Marketing peut se produire dans n'importe quelle situation où des besoins coexistent avec la capacité de fournir une réponse à ceux-ci. Compte tenu de ce large spectre, il n'est pas surprenant que le Marketing soit également présent dans le secteur de la santé. En se concentrant davantage sur le domaine des Essais Cliniques, les recherches effectuées ont démontré la pertinence croissante des approches Marketing, et plus particulièrement, la manifestation et l'importance croissantes de la partie promotionnelle de la composante opérationnelle du Marketing.

Le succès des Essais Cliniques peut être menacé par une pléthore de raisons, la préoccupation concernant le recrutement et la rétention des participants se distinguant comme l'un des principaux défis. Les « trialists » recourent à différents outils de Marketing pour aider au recrutement et à la rétention des volontaires de l'essai. Les recherches effectuées montrent que malgré les différents supports et plateformes où ces outils peuvent être intégrés, le meilleur « mix » est généralement recherché pour assurer une efficacité maximale. Enfin, la diffusion du Marketing à travers les différents processus des essais cliniques a été explorée. Actuellement, il est principalement utilisé dans le recrutement et la rétention des patients, mais avec la complexité et la concurrence croissantes des essais, certains sponsors s'aperçoivent que le Marketing pourrait être infiltré dans l'ensemble des segments des essais cliniques. La recherche effectuée a révélé que cette façon de penser pourrait avoir de l'avenir mais à l'heure actuelle est encore à un stade précoce, principalement en raison de son coût et des efforts demandés.

## **Summary**

Marketing can occur at any situation where needs or wants coexist with the ability to provide an answer to these. Taking into account this broad spectrum, it is no surprise that Marketing is also present in the healthcare industry. Further focusing into the Clinical Trials domain, the research performed demonstrated the growing relevance of Marketing approaches, and more specifically, the increasing manifestation and importance of the promotional part of the Marketing's operational component. Clinical Trials' success can be menaced by a plethora of reasons, with the concern regarding the recruitment and retention of participants standing out as one of the main challenges. Trialists recur to different marketing tools to assist on recruitment and retention of trial volunteers, with the research performed showing that despite the various supports and platforms where this materials can be embedded, the perfect mix is usually sought to ensure maximum efficiency. Finally, the spread of Marketing throughout the Clinical Trial endeavor was explored. Presently it is mainly used in patient recruitment and retention, however with increasing trial complexity and competition, some trialists are realizing that Marketing could be infiltrated into the entire clinical trial segments. The research performed revealed that this way of thinking might gain a place in the future but it is still at an early stage, mainly due to cost and effort considerations.

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## **1. Introduction**

In a broad manner Marketing has the potential to occur in every setting where there are identified needs and wants from one side and ability to provide an answer to those needs and wants from the other. Seen this wide spectrum of applications, it is less surprising that one could think, that Marketing can and is present during planning and execution of many Clinical Trials worldwide.

Clinical Trials are designed to study the efficiency of new tests and treatments on human health outcomes. This would not be feasible without the participation of volunteers in order to assess the efficiency of the test or treatment in study, consequently creating a want for subject recruitment.

With these considerations in mind, the work developed aimed to research on the existing link between Marketing and Clinical Trials and more specifically the usage of Promotion, one of the four components of Operational Marketing, on the recruitment and retention of Clinical Trial participants. Furthermore, there was also the intent to provide a field based view on this thematic as well as possible hints on how some of the researched aspects will develop in the future.

This work was performed recurring to literature review and interview of an expert in the field of pharmaceutical marketing, well experienced in the usage of promotion strategies aiming to stimulate and boost the recruitment and retention of potential participants into Clinical Trials.

## **2. Marketing – Brief History, Definitions and Components**

### **2.1. Brief History**

Marketing as we see and understand it these days, from a temporal perspective, it is relatively recent. However, if we provide an increased focus to the act of a possible exchange and associated communication of a product or service between a person with a want or need – consumer - and a person able to provide for it – producer - than marketing can be seen in some ways as old as the civilization.

Inspite of this logical premise, according with Berghoff and colleagues (Berghoff, 2012) pinpointing the historical origins of Marketing and its founders has no overall concertation nowadays.

Periods of marketing history are contested and with no consensus on where to start, with some authors claiming that the history of modern marketing began in the Middle Ages or the early modern period, however most concentrating on the nineteenth and twentieth centuries without agreeing in a specific modeling of stages.

As for Marketing and its originating ideas, there is also no accepted developmental model on how the subject evolved, or who its founding fathers were is also contested, notwithstanding

its establishment as a discipline occurred in the late nineteenth century, when the first lectures were given at American universities gaining momentum when in 1902 the first marketing courses were introduced (Berghoff, 2012).

Despite the lack of consensus on its origins and development, fast forwarding to more recent times, we can divide the presence of Marketing and potential evolution in three main eras: production, sales, and marketing as we know it nowadays.

The production era dates from the late eighteenth and nineteenth centuries, correlating with the Industrial Revolution. In this time period there was a passive marketing, product oriented, (Lambin, 2008) where the concept related with reduced or absent competition and high demand, having two main questions in focus – “can we produce it? And can we produce it in enough quantity?” This simple reasoning worked particularly well at those times thanks to a production concentrating in goods of basic necessity and on the existing high demand as above mentioned.

With this era characteristics, the effect of its mass-producing with years passing, lead to a demand decrease creating the terrain for a sales concept to establish.

In this period - mid-twentieth century – the importance of the consumer started to be highlighted, with producers aiming to answer to two different questions – “can we sell it? And can we charge enough for it?” At this point the role of the sales oriented operational marketing became more active having as mission to prompt product commercialization. Despite more present, there was still a disregard for understanding what were the consumers’ needs or desires but producers started to address directly to them through advertising and personal selling.

Finally, a transition occurred into the Marketing concept as it exists today.

In the Marketing era different key questions focusing on the consumer surfaced: “what do consumers want? Can we develop it while they still want it? And how can we keep our customers satisfied?” (Masood, 2009).

## 2.2. Definitions and Components

As testimonial of the considerable mutations Marketing suffered throughout the centuries, we can now observe that its activities have incredibly developed focusing on the importance and the understanding of the target audience, their behavior and expectations, how to create products and services able to respond to these, how to efficiently deliver messages to create awareness on them and much more.

According with the American Marketing Association (AMA), Marketing is defined as “the activity, set of institutions, and processes for creating, communicating, delivering, and exchanging offerings that have value for customers, clients, partners, and society at large” (AMA website, 2017).

Continuing on defining Marketing, it is the “set of actions aimed at knowing, forecasting and, eventually, stimulating the needs of consumers with regard to goods and services and adapting production and commercialization to the needs thus specified” (Kervyn, 2018).

Ultimately, as a subject of study, “Marketing is a management discipline that includes a system of thought, analysis and action” (Kervyn, 2018).

At the heart of Marketing there is a research for comprehending a client’s behavior. With this in mind the discipline seeks to understand the needs and wants of the potential client as well as his response process to the marketing stimuli – these can be stratified into cognitive (learn), affective (feel) and behavioral (do).

In order to translate the market’s needs into productions that are able to respond and deliver the desired, a Marketing approach can be divided in two different fronts: the Strategic Marketing and the Operational Marketing. The former will allow to orientate efforts towards the understanding of the client, whereas the latter will be concentrating on the product mix to achieve delivery of the product’s message and eventual exchange (sales).

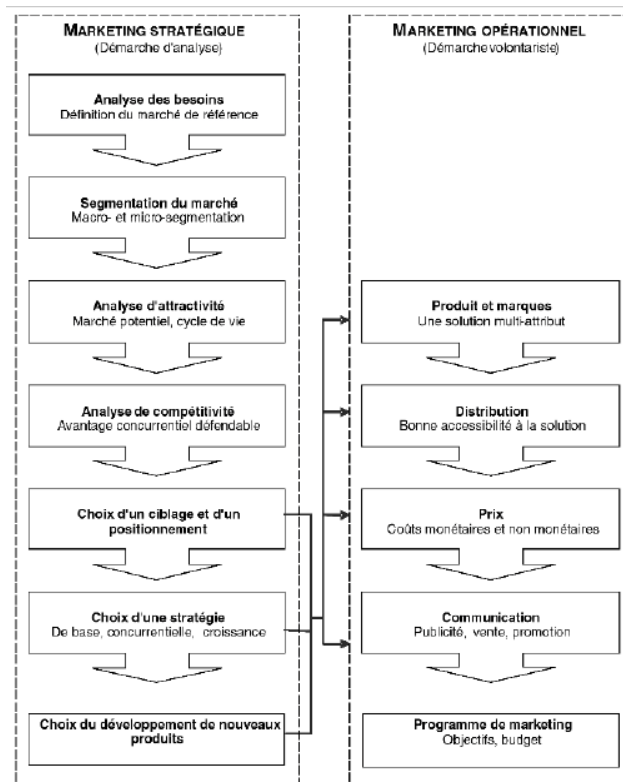


Fig.1: Components of Strategic and Operational Marketing (in French).

### 3. Strategic and Operational Marketing

As informed in Fig.1, the division in two main work streams highlights the need for market analysis (Strategic Marketing) before proceeding to a more explicit contact with the potential client (Operational Marketing):

### 3.1. Strategic Marketing

The Marketing strategy process begins by taking into account what was learned from analyzing the market needs and defining a reference market. The following step consists in a macro and micro segmentation of the reference market going from an overall conceptualization of the reference market answering to “what abilities to provide?”, “who are the different client groups?” and “how to provide a solution different from the already existing?” in order to shed light into the decisions relating to market coverage, until the more in-depth analysis of the diversity of potential clients constituting each of the markets previously identified (Lambin, 2008).

Succeeding to market segmentation a second analysis is performed on the attractiveness and competitiveness of the segmented markets. The first approach will allow to learn on the intrinsic attractions of each segment and identify the primary demand principles, which is useful in detecting opportunities of market growth. The second approach relates to competitive advantage towards the direct competition and its differentiation will allow the producer to obtain a certain market share.

Proceeding the market segmentation and further decision in a general strategy thanks to the attractiveness and competitiveness analysis, the producer must incur in choices concerning targeting and positioning. The options preferred regarding segment targeting will be influenced by the producer’s resources, its ambitions, as well as the market’s heterogeneity (relating to the dilemma Standardization versus Adaptation). With a clear choice on which segment or segments to target, a selection is needed on what positioning to adopt.

Positioning can be defined as “the act of designing a brand and its image with the aim of giving it, in the mind of the buyer, a place appreciated by customers and different from the competition” (Kervyn, 2018) and will be intimately related with the targeting process since the choices concerning standardization or adaptation need to be consistent with the ones of imitation or differentiation formed during positioning reflection.

Following this process, a transition occurs from the strategic marketing to the operational one. At this point it is of paramount importance that a coherence exists between targeting and positioning as well as between positioning and the 4 P’s of the Operational Marketing.

### 3.2. Operational Marketing

At this stage of the overall process, a strategy is already devised thanks to the analysis and choices performed from understanding the client’s need or wants until market targeting and positioning meaning that all is set at this point to prompt differentiation, creating an added value to the client through a solution adapted to his needs or wants and that is superior to the competition. The next step is to elaborate a marketing mix in line with the marketing strategy that will allow to capture and promote the solution’s unique selling points.

The marketing mix of Operational Marketing is composed of the so-called 4 P's:

**Product (or Branded Product)** – The solution, be it a good or a service, is a set of attributes that in addition to its basic functions presents a group of functions that distinguishes it from the others (differentiation). It is very important to well know the solution and its attributes before marketing it;

**Price** – The pricing choice requires the producer to respect an internal rationality associated to constraints regarding production and profitability, as well as an external one demanding that the price chosen is appropriate to the consumer's price sensitivity and also the prices charged by the competition;

**Place** – Deciding on how to place and/ or distribute is crucial for the ability to choose the most performant ways to distribute a solution according, for example, with its characteristics (ex: perishable goods) as well as the best placement locations able to increase the probability of an eventual transaction to the consumer. It is worth mentioning that with the advent of internet, the power relationships between producers and distributors is being modified and leading to the appearance of new intermediaries.

**Promotion** – Also of extreme importance are the ways chosen to inform the potential consumers on the solution. The dissemination of information can be performed through different means, from social media to search engine marketing, advertising to public relations, sales forces to video marketing and further. When elaborating a communication plan, four tasks are to be performed: defining objectives, create the message, choose the media plan and measure the communication's efficiency.

Recurring to the definition of Marketing by the AMA, Marketing can be seen as containing a process for communicating offers that have value for customers, clients, partners and society at large. With this in mind, seen the possibility to be used in a broad range of fields, it is no wonder that its presence can be commonly observed in the development and unfolding of a Clinical Trial, especially the resource to the Promotion component of Operational Marketing aiming to aid on the implicit obstacles in recruiting and retaining clinical trial participants.

#### **4. Clinical Trials – Definition, Developmental Phases and Challenges**

##### **4.1. Definition**

The World Health Organization (WHO), defines clinical trials as “a type of research that studies new tests and treatments and evaluates their effects on human health outcomes (...)” (WHO website, 2020). As additional definition, a Clinical Trial “(...) is any research study that prospectively assigns human participants or groups of humans to one or more health-related

interventions to evaluate the effects on health outcomes. There is a large number of regulations which regulate the procedure of clinical trials and their marketing activities” (Stamenovic, 2018).

#### 4.2. Developmental Phases

A medical product, depending on its characteristics along with extrinsic considerations, will in general undergo a sequential development to allow investigators to fully ascertain its attributes, effects in humans and, depending on the successive results, receive an approval to be marketed. As a small remark, despite the general clinical development parameters being transversal to pharmaceuticals or medical devices, the phases announced below are closer to the processes a study drug goes through.

In order to establish a first view on the product in hand, an introductory preclinical development is executed. At this stage, the idea is to learn and withdraw primary insights on the effects and efficiency before passing to a first-in-man study. At this point studies on pharmacokinetics, pharmacodynamics and toxicology are performed, usually having animals as population.

An initial phase “*nulla*” is performed in a human population with small study drug doses to ensure safety and confirm that the data on pharmacodynamics and further parameters obtained from the pre-clinical development remain similar or unchanged.

A phase I follows having a reduced sampled population. From this moment on, safety is a major endpoint and a range of different dosages (in case of a pharmaceutical drug) are tested, trying to ascertain its lowest and highest values regarding efficiency and safety repercussions.

Usually 70% of the medications pass on to a phase II where the sampled target population is increased as well as the treatment length. The safety of the product is still not completely established to generalize into a general population however the results and conclusions (if positive) will allow to devise the foundations to design a succeeding phase III – the Food and Drug Administration (FDA) estimating that 33% of the products in study are able to advance into phase III.

Phase III is the one with the largest sample population (before eventual market authorization). This trial stage will provide the data needed to confirm all the hypothesis on product’s efficiency and safety formulated so far and assess if it is at least as safe and effective as other similar market authorized products.

Finally, if the product was able to demonstrate safety and effectiveness, submissions are performed to the health authorities requesting an approval for marketing authorization. Subsequent to marketing authorization approval, a phase IV can be conducted to continuously assess the long-term safety in a wider population, its overall effectiveness, and potentially learn on other study drug’s benefits (FDA website, 2018).

### 4.3. Challenges

A clinical trial due to its inherent characteristics, independently if related to the pharmaceutical or medical device sectors, presents many opportunities for failures.

The primary source of failure relates to the eventual inability of the test or treatment in study to demonstrate efficacy or safety. Reasons as a flawed study design, inappropriate statistical endpoints or insufficient sample size are some examples. Another failure source is the financial impact, with 22% of the unsuccessful phase 3 studies failing due to lack of funding with implicit likelihood of missing the enrollment needed to demonstrate statistical significance at a predefined level of efficacy. A third source relates to the protocol's eligibility criteria. The inclusion and exclusion criteria should result in a sampled population matching the general population in study however the protocol's design must account for additional concerns as for example the comorbidities linked to particular segments of the target population that can increase the risk of adverse events or withdrawal. Following the criteria for eligibility of a sample of the target population, patient recruitment surfaces as another opportunity for Clinical Trial failure. According to Fogel (Fogel, 2018) "patients are often willing to consent to participation in a clinical trial if they believe that they have an opportunity to receive better treatment or if the results can help the others. Still, failing to enroll a sufficient number of subjects in a trial is a long-standing problem."

Under the umbrella of recruitment issues, it is also source of failure the additional costs associated with recruitment which are difficult to estimate and highly variable even within the same investigative area. Additionally, obstacles regarding the patient's concerns are source for potential fallibility, meaning that there is a negative correlation between randomized placebo controlled trials and patient recruitment and retention since potential participants are not eager to risk being assigned to the placebo group instead of the active treatment, and moreover the general population might have difficulties understanding information about clinical trials due to limited scientific literacy. Still on enrolling potential participants, a poor recruitment, high rate of participant dropout and inability to achieve the trial's statistical power as per design (due to lack of sufficient sample) are also sources of failure – one of the problematics related to these sources is the possibility (more of a recurrent pattern in reality) that the selected study centers overestimate their enrollment predictions leading to below average recruitment rates - the so called Lasagna's law phenomenon.

Furthermore, a clinical trial also presents a failure risk if quantitative measures are dismissed, if the financial impact to patients participating in a trial is overlooked - even if all trial-related procedures are paid by the trial's sponsor, other costs as transportation expenditures or loss of working hours can occur - and the inability for taking into account the participant's time investment can also be an opportunity for failure since the willingness for a potential participant to enroll in the clinical trial is intimately related to the distance between a participant's home and the study center's location (Fogel, 2018).

In an overall retrospective, from the 10 main opportunities for clinical trial failure above mentioned, 40% of them relate directly or indirectly to issues concerning recruitment and retention of clinical trial participants.

Seen the main threats to a successful clinical trial, it is possible to affirm that the recruitment and retention of Clinical Trial participants represents an important hurdle to Clinical Trials unfolding. As written by Gul and Ali (Gul, 2010) “recruitment and retention of appropriate and sufficient number of participants in research are serious methodological concerns, as they influence the validity of the research findings (...)” and proceeds “scientific consequences of under-recruitment include a reduction in the statistical power of a study; sufficient sample size is required to ensure adequate statistical power.” Frandsen and colleagues also affirmed that one of the greatest challenges for researchers is recruiting eligible and representative participants to their studies (Frandsen, 2016).

### **5. Marketing in Clinical Trial Recruiting and Retaining**

It is now clear that from the multiplicity of factors able to induce the success or failure of a clinical trial, recruitment and retention of eligible participants is key in obtaining the desired trial unfolding. With the intent to ensure an efficient recruitment and retention of trial volunteers, Operational Marketing strategies have been applied for some decades now. Unfortunately it was not possible to pinpoint the exact year where a first clinical trial was advertised in order to prompt recruitment, however in the United States this practice has likely established itself in the late decades of the twentieth century – inferring a possible parallel time period with the advent of the Direct-to-Consumer Advertising (FDA website, 2015).

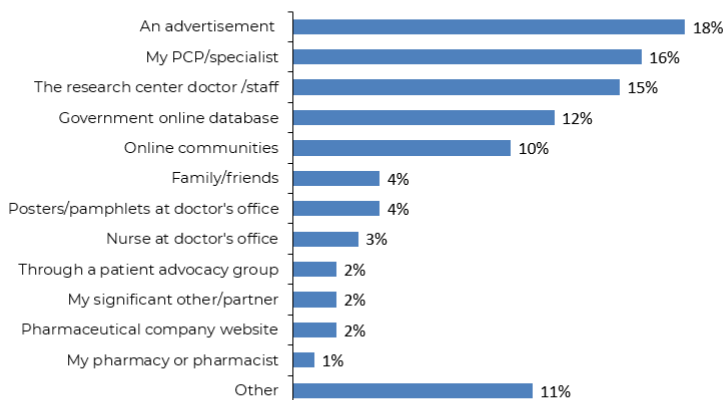
The body of literature on the use of Marketing strategies for Clinical Trial recruitment is still reduced as well as the reporting on its efficiency, however an increase in the late years can be observed, as for example the research developing on the adoption of social media as a recruitment method, or the understanding of what potential trial participants expect from the recruitment materials. In the meanwhile, investigators are beginning to recognize the need for Marketing strategy implementation in Clinical Trial design and development. As Fogel clearly stated “the degree to which professional marketing expertise has been applied to help promote clinical trials is difficult to ascertain presently, but deserves specific research attention” (Fogel, 2018). Interestingly, already in 2002, Rowe and colleagues had mentioned that “to get patients into trials more efficiently pharma companies must begin to think like marketers” (Francis, 2007).

### **6. Operational Marketing: Advertising for Clinical Trial Recruiting and Retaining**

It is relevant to inform and discuss the existing advertisement methods used in clinical trial recruitment and retention - the main reason being that in a setting where recruiting and

retaining is arguably the main challenge in clinical trials, of the widespread means to learn on existing clinical trials, advertising is probably the main source. In 2019, the Center for Information and Study on Clinical Research Participation (CISCRP) reported that 18% of the American population was aware of a clinical trial thanks to advertising:

## Top sources where people learned about clinical research studies



Source: CISCRP, 2019 | Base: Those who have participated in a clinical trial | n=3,654

Fig.2: Sources where people learned about Clinical Trials (CISCRP, 2019).

Traditionally, commonly used recruitment strategies include printed media as for example newspapers, flyers and brochures, but also radio, face-to-face events (country or health fairs), and informal channels such as word of mouth (referrals). Of course each strategy carries its benefits and limitations.

**DO YOU SUFFER FROM ARTHRITIS OR WEAR AND TEAR ARTHRITIS?**  
**DO YOU HAVE TO TAKE REGULAR PAINKILLERS?**

If so, you are not alone. More than nine million people suffer from arthritis or wear & tear in the UK and take drugs such as ibuprofen and diclofenac, called NSAIDs, for pain relief.

NSAIDs relieve pain but can also cause side effects such as indigestion, stomach ulcers and problems with the heart and circulation.

The SCOT Trial has been launched to compare the safety of different types of NSAIDs and find the best treatment for this painful condition.

GP Practices across Scotland and Denmark are taking part.

If you are aged 60 or over and are currently taking NSAIDs for arthritis or wear and tear, you may be able to help with this research.

Contact: **0800 917 3509**  
 or visit [www.scottrial.co.uk](http://www.scottrial.co.uk)  
 for further information.

Logos for participating institutions: Dundee, University of Aberdeen, University of Glasgow, and the University of Nottingham.

Fig.3: Example of newspaper advertisement for Clinical Trial Recruiting (Arthritis study)

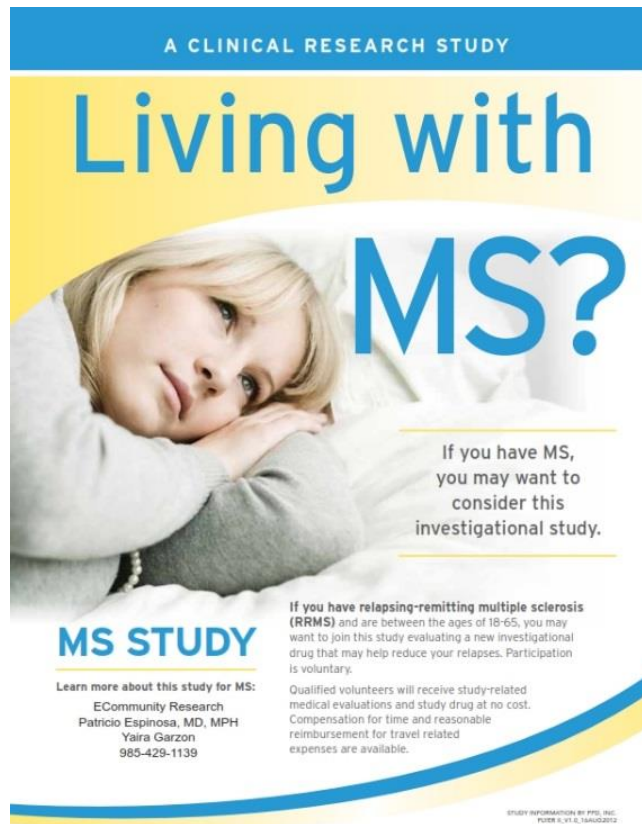


Fig.4: Example of flyer advertisement for Clinical Trial Recruiting (Multiple Sclerosis study).

As examples, on the benefits side, radio and newspaper advertising for Clinical Trials usually have a large reach presenting the potential ability to generate a high number of first contacts with potential trial participants, however as limitations, they have a limited space (newspaper) or time (radio) to share all important study details which may lead to a prejudicial bias on the interpretation by the message receiver which can prompt the person to simply opt-out or eventually being deemed ineligible by the study staff resulting in a poor channel efficiency. In addition, these advertisements are usually inflexible because once an advert has been fixed, it can be very expensive and difficult to change (Frandsen, 2014).

Research has been performed with the purpose of acquiring a better grasp on what potential clinical trial participants look for on overall recruitment materials, with a logical conclusion that a clear, unambiguous, trustworthy information remains a valued prerequisite (Shneerson, 2013). Nonetheless, even if the recruitment materials take well into account what they forcibly need as main characteristics, each recruitment strategy will have limitations that jeopardize a higher efficiency, hence the propensity to infer that a Clinical Trial recruitment and retention campaign needs to be composed of different advertising supports.

The emergence of social media, and especially Facebook, opened the doors to an additional method permitting the recruitment into Clinical Trials.

**Fred Hutchinson Cancer Research Center**  
 You cherish your time with your children. So you're going to quit smoking.



**You want to be there for your kids.**  
 webquit.org  
 Join the Fred Hutchinson Cancer Research Center's free quit study!

Like · Comment · Share · 679 42 264 · 14 hours ago ·

**Centre for Research in Family Health**  
 March 23, 2015 ·

Does your child have FASD (Fetal Alcohol Spectrum Disorder)? Do you struggle with challenging behaviours?



**FASD Study**  
 Are you experiencing challenging behaviors with a child diagnosed with Fetal Alcohol Spectrum Disorder? You may want to part in a new study. [Visit FASD](#)

Parenting Children with Fetal Alcohol Spectrum Disorder :: MyStudies  
 myStudies is an online tool for managing research activities.  
 MYSTUDIES.CA | BY CONNIEC

**Centre for Research in Family Health**  
 October 13, 2015 ·

Does your child have FASD? Do you struggle with challenging behaviours? You may want to take part in our study for parents and caregivers of children age 4-12 living in Canada. Visit <https://mystudies.ca/studies/fasd> to see if you are eligible to take part.



**Centre for Research in Family Health**  
 July 3, 2015 ·

Summer plans? This may be a great time to check out the Strongest Families FASD Study!  
<https://mystudies.ca/studies/fasd>



Parenting Children with Fetal Alcohol Spectrum Disorder :: MyStudies  
 myStudies is an online tool for managing research activities.  
 MYSTUDIES.CA | BY CONNIEC

Fig.5: Example of Facebook advertisements for Clinical Trial Recruiting (Smoking Cessation and Fetal Alcohol Spectrum Disorder studies).

Specifically discussing on Facebook's utility, its intrinsic capability on facilitating access to an extensive group of potential trial participants is with no doubt a main strength, being one of the most frequently visited sites on the Internet and the most popular social networking site in the world (Frandsen, 2014).

Further to its wide reach, social media in general allows a bigger flexibility on the alteration of messages transmitted (if needed), ability to control advertising duration and day-to-day expenditures, all these being difficult or plain impossible to translate into more traditional recruitment or retention methods. Also of regard, there is also the possibility to target the population sought by the Clinical Trial increasing the advertisement's efficiency.

In an opposite point of view and as abovementioned, all trial recruitment methods present also their limitations and social media is no exception. Social media users, in the case of Facebook for example, tend to be female and under 30 years old, however there is increasing evidence that the disparity in gender and age is lessening with expanding mainstream usage.

Furthermore, from previous research in Clinical Trial recruiting, social media (and particularly if paid advertising is used which is common within the health sciences) tends to be more expensive than the traditional methods, but once again the balance cost-benefit might be more adequate than expected seen its positive attributes.

Despite these assumptions, “(...) data on social media recruitment’s effectiveness compared with more traditional methods is limited” (Frandsen, 2016) even because ultimately, the efficiency of a recruitment strategy in clinical trials is not only the ability to engage and lead to the enrollment of people willing to volunteer but also the capability of retaining them until study completion.

Although advertising methods are the main source for learning about clinical trials, it is worth mentioning the importance on the referring of potential participants performed between health care practitioners and word of mouth. Not only this source is second in line with 16% (Fig. 2) as it also contains a feature potentially less remarked on other methods –

Trustworthiness. When the emitter and receiver of the message are closely related or if the relation is between health practitioner and patient, the element of trust is further present increasing the probability of the receiver “buying into” Clinical Trial participation.

Finally, it goes without saying that in a setting where human beings are incurring in an experiment, all steps and ramifications of a trial are under strict regulation by the health authorities, necessarily comprising the clinical trial recruitment methods and their content. As an example, in the United States, the FDA disposes of a clear guidance directed to the Institutional Review Boards (IRB) and Clinical Investigators on how to recruit study subjects. The guidance clearly stipulates that “(...)the IRB should review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting subjects is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol” (FDA website, 2018). It is also noteworthy that the guidelines stipulating the allowed methods and content for recruiting advertisements in clinical trials can vary considerably from country to country.

## **7. Marketing a Clinical Trial**

As demonstrated, the employment of Operational Marketing, focusing on its promotional component, has been used throughout many clinical trials with the intent of inducing an efficient recruitment and retention of potential trial participants. The most traditional methods going from advertisements in journals or dedicated flyers until the more recent approach through social media channels.

If a relation is made, whilst having these methods in consideration, with all the steps Marketing encompasses from knowing the consumer, segmenting the market, targeting and positioning, culminating in a group of elements and information to sustain the development of an operational process, it is clear that trialists do not take the topic of marketing their trials lightly, surely recognize its importance, and incur in various endeavors to understand the target population needs to induce recruitment and retention efficiency. This work focused primarily in promotion and its importance in clinical trial recruitment, nonetheless it is important to mention that from the research performed it stood out the reduced amount of literature intending to systematize a complete Marketing approach in Clinical Trials. In other words, there is evidence on the usually seen recruitment and retention needs and challenges (especially in phase 3 trials) as well as the promotion efforts to diminish these, however the body of literature informing on a more holistic process on how to market a Clinical Trial seems thin.

Despite this shortage, Francis and colleagues (Francis, 2007) published research on the presence of Marketing in Clinical Trials with the purpose of providing and inciting a more complete perception where it is recognized that “clinical trials require strategy, management, marketing and sales” (Francis, 2007). In other words, trying to look to a trial from a business perspective to assess its Marketing strategy.

With this in mind, according with the research of Francis and colleagues (Francis, 2007), it can be considered that the activities for Marketing a Clinical Trial can be grouped in five stages:



Fig. 6: Five stages in Marketing a Clinical Trial.

The first stage – Set-up – relates to legitimacy efforts to achieve the buy-in of the health authorities and stakeholders as well as buy-in from opinion leaders in the studied field. At this point, the idea is to embed a marketing perspective within the trial and devise robust systems to ensure that the marketing activities are performed efficient- and effectively whilst following the trial’s goals.

The second stage – Market Planning – as depicted in Fig.6, represents the segmentation of the interest markets. Here it is intended to discover what would encourage people to volunteer into a clinical trial, develop a “value proposition” and prompt the setting where the whole clinical trial organization works within the Marketing spectrum.

The third stage – Signaling – is about transmitting in a complete and persuasive manner the “value proposition” to enough people in the target market as well as to the principal

investigators and site staff (intermediaries), regulatory bodies and any remaining actors that can help or hinder the trial. Here we can make the correlation with promotion in Operational Marketing.

The fourth stage – Learning – as its title indicates, is about awareness of what is going on in the targeted market and use this knowledge to develop better practices, evaluate it and if needed review the clinical trial's strategy.

The fifth and final stage – Reinforcing – is where it is ensured that the commitment for support of the overall parties remains sustained.

These stages remain somewhat theoretical and potential adaptations will be needed depending on the characteristics of the product, Clinical Trial phase, actors involved and further.

Nevertheless these five phases clearly demonstrate that a trial to better perform, is required to include its clinical component but also a business one, which will allow to see clinical trials as they are: highly complex projects but also businesses. Their need for volunteers can be mirrored as their “need to find customers.”

## **8. Interviewing Mme. H - Field Expert**

The reviewed literature permitted to learn about the presence of Marketing and its promotional element in Clinical Trials, the different methods used, and also allowed to perceive an unbalance between the amount of research seeking to increase knowledge on the methods used for advertising a trial hence aiding recruitment and retention, and the amount of research looking to how a clinical trial can have the Marketing approach as a whole.

Since the overall considerations arose mainly based in literature research, it is of interest to include a more practical and realistic perspective on some of the aspects relating to the overall thematic treated above.

With this in mind, the author of this work had the opportunity to question an expert in the field of Pharmaceutical Marketing. Mme. H focuses in pharmaceuticals and clinical research having a deep knowledge and experience when it comes to Marketing in Clinical Trials, advertising for trial recruitment and retention, brand management and related business development. The following section – Discussion – presents elements researched from the literature along with insights received from this interview. The complete interview with Mme. H. can be consulted in Annex 1 (Page 20).

## **9. Discussion**

Following the literature researched and insights from Mme. H., it is possible to affirm that clinical trials face different opportunities for failure with recruitment and retention remaining main challenges to be confronted. As mentioned by Mme. H. during our interview “recruitment

and retention are certainly two of the largest issues facing Sponsors when it comes to late-stage clinical trials. Phase 3 trials require a highly qualified type of patient, and oftentimes hundreds, if not thousands of them. Ideally, the sooner a Sponsor can close enrollment, the sooner they will be able to meet their endpoints.”

The inability to achieve the proposed enrollment targets can lead to considerable negative repercussions and eventually, Clinical Trial collapse. These perceived risks reinforce the importance of using Marketing techniques to not only tackle recruitment obstacles but also to aid on patient retention since dropout rates of 30% or more can occur throughout different trials (as observed by Mme. H.).

It was also possible to perceive that the increasing clinical trial complexity and competition between trialists (sponsors) is facilitating the embracing of Operational Marketing methods, more specifically their promotion through advertisement, in order to sustain desired recruitment and retention rates. Notwithstanding, this embracing is evolving slowly with many sponsors still relying considerably on site patient database's, increasing the impact of the Lasagna law's effect. In addition, the advertisement field is highly regulated still creating reticence for trialists in using these methods. These affirmations being aligned with the literature researched were well mentioned by Mme. H.: “while many sponsors are more and more inclined to look to advertising to fill recruitment gaps, the pace of that change is still relatively slow, as many sponsors and CROs continue to rely on sites to provide the only pipeline of patients for their trials.”

Despite the gradual advancing of advertisement use for trial recruitment and retention, this tendency seems here to stay even because as previously indicated nowadays this is the number one method the population recur to learn about clinical trials and again with increasing trial complexity and competition finding qualified patients becomes harder, prompting the need for advertisement methods.

Further diving into the advertising tools, the array of choices has widened with the advent of social media. From the gathered research, these tools can go from the traditional methods as word of mouth, paper support materials as newspapers and flyers, passing by radio and television advertisements and finally extending into the latest resource – social media channels. The usage of Facebook, Instagram and other platforms allow the trialists to more efficiently target the population sought for the Clinical Trial in hand, is adaptable in an ongoing basis and capable to reach a massive audience in a short period of time. In spite of this benefits, all recruitment materials available nowadays in the “advertisement toolbox” present their own benefits as well as limitations, contributing to the thought that a campaign launched to aid in patient recruitment and retention for a clinical trial, needs to constantly have in mind the targeted segment – fundamental in Marketing – and also consider the therapeutic area, the product being tested and further. Extracting from Mme. H.'s interview: “(...) because all studies are different, it is impossible to standardize a one-size fits all approach to recruitment, including the advertising platforms used to reach the intended audience.”

Ultimately the correct mix of recruitment materials is key for attaining the desired patient recruitment and retention rates through advertising.

Finally, despite the growing establishment of Marketing and its methods in the Clinical Trial process, its presence still stays mainly circumscribed to the promotional efforts of its operational component. Some trialists, again due to competition and augmenting trial complexity, are starting to realize the potential behind looking to a clinical trial not only from a clinical, but also business approach. Nevertheless, as also observed by Mme. H: “some sponsors appreciate that this new era of increased competition and complex studies require a more focused approach that includes marketing a study as a brand. However, the cost and effort required to engage in this type of recruitment campaign currently makes this type of robust approach an outlier in the industry”, hence revealing that this holistic way of seeing Marketing in clinical trials remains more of an exception to the rule.

## 10. Conclusions

The body of literature researched, combined with a more realistic point of view given by the participation of a field expert in Pharmaceutical Marketing, allowed us to corroborate that nowadays the execution of Clinical Trials is highly complex with patient recruitment and retention being of paramount importance due to its character as a main challenge during clinical trial unfolding, as well as its ability to lead a Clinical Trial to failure if its condition is not satisfied.

This increasing trial complexity and growing competition between trialists, along with the clear importance given to patient recruitment and retention is leading to a bigger investment and consideration on the importance of Marketing as a field of interest to conduct a clinical study, with its promotional aspect being used through advertisement methods to aid in the awareness of ongoing Clinical Trials as well as in recruitment and retention of volunteers much needed for trial success. The available recruitment materials exist in different supports, with each of these presenting advantages and limitations. The research performed demonstrated that a mix of this materials according with the target population, product and therapeutic area along with additional factors remains the standard approach to efficiently counter the challenge behind recruiting and retaining clinical trial volunteers.

Ultimately, some trialists begin to realize that Marketing should be applied to a clinical trial in a more holistic form, postulating that the approach to achieve trial success should be clinical but also business-wise – as mentioned before, a Clinical Trial always “needs its clients to buy-in.” Despite advancements in this area, this way of proceeding remains an outlier with much of the Marketing in a clinical study being present on its advertisement and search for new patients or ensuring that the ones already enrolled remain.

Marketing is a field that can be present at any situation where a consumer, producer and potential exchange meet, meaning that its presence in Clinical Trials is no wonder and, in addition, all indicates towards its growing and eventual infiltration into the different departments a Clinical Trial is composed of, increasing the probability for Clinical Trial success. Interestingly in the same way Marketing first evolved in its operational component

independently of the industry in discussion, here too promotional endeavors are further settled (in the trialists side) than the whole strategic and operational faces.

Looking into the future, one could infer that Marketing will become more and more entrenched in the Clinical Trial day-to-day activities whilst multiplying its forces and platforms to promote not only recruitment and retention efforts but success in overall. Possibly its mutation into a more holistic form will occur the moment all trial parties fully realize that in the phrase “a person in search of care”, the part “in search of” creates an opportunity that can be turned into increasing success.

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## Annexes

### Annex 1: Integral Interview with Mme. H. – Field expert

R.P.R.: Mme. H thank you for your availability for this interview. As you are aware, this work revolves around the thematic of Marketing in Clinical Trials. More specifically, the challenges concerning recruitment and retention, as well as the usage of Advertising methods to tackle this. Before going further into the subject, could you tell us a bit about your professional career and what your job consists of?

Mme. H.: Certainly. I am a Senior Account Leader at a global patient recruitment and retention company based in Chicago. We provide fact-based patient recruitment and retention solutions grounded in patient insights for primarily Phase 2 and 3 clinical trials. As a member of the Account team, I serve as the main point of contact for the client (Sponsor) and oversee cross-functional teams internally to ensure the project is on track and we are meeting client needs according to the scope of work for the program. I have been at the company for almost three years and have worked on a number of Phase 3 studies across multiple therapeutic areas. The company I work for actually originated from a larger marketing company, which is why all of our service offerings are consumer (patient) focused.

R.P.R: Mme. H. thank you for this introduction. Seen your experience with Marketing in Clinical Trials, would you agree that recruitment and retention can arguably be the main challenge in clinical trials (especially in Phase 3)? How do you see this problematic?

Mme. H.: Recruitment and retention are certainly two of the largest issues facing Sponsors when it comes to late-stage clinical trials. Phase 3 trials require a highly qualified type of patient, and oftentimes hundreds, if not thousands of them. Ideally, the sooner a Sponsor can close enrollment, the sooner they will be able to meet their endpoints. However, this is seldom the case, with a majority of Phase 3 trials being delayed due to sites not meeting their enrollment targets. This is a problem because the massive investment required to initiate and complete a Phase III study means that any timeline delays result in a significant cost to the sponsor. Similarly, with retention, Phase 3 trials can sometimes experience higher than 30% drop out rates. While patients are able to drop out at any point in time, for any reason, strategic marketing and messaging can help identify highly motivated patients that are more likely to not only take action but are also more likely to remain engaged through the completion of the trial.

R.P.R.: Indeed the repercussion on the clinical trials' endpoints and timelines due to failure in enrolling a sufficient number of participants in a timely manner is tremendous. Going further into the Marketing field in general, and its operational component in particular, the research

performed indicates that trialists are becoming more attentive to the advertisement component of their trial. What is your view?

Mme. H.: The increase in the numbers of trials conducted globally in recent years, coupled with increasingly complex protocols, means that there is growing competition to find qualified patients to participate in research studies. This fact has resulted in more sponsors realizing the need for advertising to augment the number of site database patients recruited for trials. While many sponsors are more and more inclined to look to advertising to fill recruitment gaps, the pace of that change is still relatively slow, as many sponsors and CROs continue to rely on sites to provide the only pipeline of patients for their trials. Additionally, because clinical trial advertising is still a relatively new and highly regulated (not to mention, ever evolving) service, we have sometimes seen trialists have reservations about launching a full-fledged media campaign, especially on a global scale. Certain countries still do not permit the use of any patient-facing materials (be it traditional or online) as they can be viewed as coercive. So, while I believe trialists are more receptive to the idea of having advertising for their clinical trial, I think there are still certain limitations and barriers to entry to overcome, especially as it relates to recruitment. In addition to providing more promotional-focused materials to recruit patients, it is also increasingly important to also provide patients with educational materials throughout the trial. This is another way of maintaining patient engagement and retention. If trialists think about their study more as a brand that patients can engage with and understand, they will have an easier time recruiting and retaining.

R.P.R.: Still on the promotional topic, as demonstrated in the CISCRP graphic (Fig. 2), do you think that advertising will continue to be the number one method for aiding clinical trial recruitment and retention? Do you think its share might increase in the future?

Mme. H.: As patients become harder to find, due to increased competition and more complex protocols, it stands to reason that more and more advertising will be needed to recruit patients to clinical studies. While it is the number one method as noted in the CISCRP research, general awareness of studies continues to be a significant barrier for the industry, further bolstering the need for advertising to engage the number of patients needed to enroll in both current and future trials.

R.P.R.: Well understood, thank you. Going into the advertisement tools that are available to face this challenges, the advent of social media originated a new way for recruiting and retaining in clinical trials. Do you think in the future, strategies using only social media will be preferred or a mix with the traditional methods (radio, newspaper, flyers, etc...) will continue to be the standard?

Mme. H: This is a great question – and one our business is always asking as well. The “marketing mix” varies study to study based on therapeutic area, target patient, study

requirements, and various other factors. In recent years however, we have certainly seen the success of recruiting patients via social media platforms like Facebook, Instagram and Snapchat. If you think about it, almost everything in today's day and age has gone digital. Humans in general have changed the way they obtain information. More and more individuals are relying on social media as a platform not only for keeping connected with friends and family, but also as a means of finding information, consuming their news, sharing ideas, forming opinions and so on. While there are certainly benefits of having traditional assets (radio spots, newspaper ads, flyers, brochures) for a full cohesive campaign, online advertising provides a relatively lower cost method for reaching large numbers of potential patients in a short amount of time. We can better pinpoint our exact target based on their online behaviors, we can reach the same viewer across multiple different platforms, track how potential patients are interacting with the ads and optimize our strategy around that. We can also be more efficient with our targeting as well, by being able to focus our advertising on a certain subset of the population, who is more likely to resonate with our messaging and take action. However, because all studies are different, it is impossible to standardize a one-size fits all approach to recruitment, including the advertising platforms used to reach the intended audience.

R.P.R.: I see the social media became an established additional tool in the array of choices to reach potential participants. Thank you very much Mme. H.

To conclude, a final question less related to promoting a clinical trial *per se*, and more about Marketing as a whole in clinical studies. Do you think trialists are starting to acknowledge that their trial could be interpreted as a brand to be marketed and hence less focusing on advertising-only to tackle recruitment issues? In your opinion is there still a long way to go or is this mindset already here?

Mme. H.: Some sponsors appreciate that this new era of increased competition and complex studies require a more focused approach that includes marketing a study as a brand. However, the cost and effort required to engage in this type of recruitment campaign currently makes this type of robust approach an outlier in the industry. As the industry continues to evolve and sponsors become more attuned to the next for more patient-centric engagement, it seems likely that this approach will become more the norm in global research.

R.P.R.: Thank you very much Mme. H. for your availability and valuable insights.

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