Recruiting diverse populations for clinical studies

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We have a duty to do all we can to create materials that

AID THE RECRUITMENT PROCESS ACROSS DIVERSE POPULATIONS

by overcoming barriers and facilitating the process.

Recruiting diverse populations

Ethnic and religious minorities tend to be under represented in global clinical studies. For example, African Americans represent 12% of the U.S. population, but only 5% of clinical study participants.

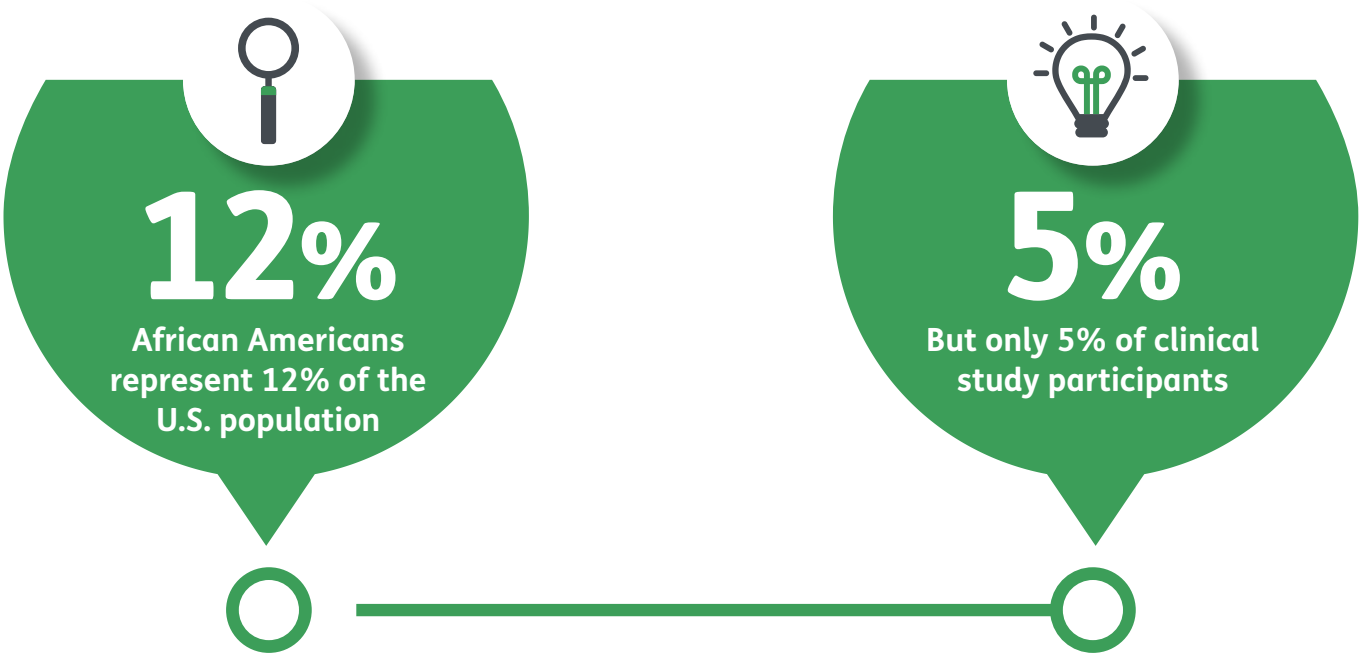

Figure 1: Under representation of ethnic minorities

At the same time, regulatory bodies around the world are increasingly asking drug manufacturers to provide evidence of drug safety and effectiveness in diverse populations when they submit applications for marketing authorisations.

We therefore have a duty to do all we can to create materials that aid the process of recruitment across diverse populations for our clients; overcoming barriers and facilitating the process.

The following guidance is provided as an aid to address this need and sets out some principles that we should all be aware of. As always, we must communicate the content of study protocols and their informed consent documentation accurately and without emphasising or minimising risks to potential participants.

Transparency, honesty, and clarity

While those of us involved in the health communications industry believe that we always write to the highest standards of transparency and honesty, those we are communicating to do not necessarily share that belief. There can be a lack of familiarity with the clinical study process and even distrust of pharmaceutical companies (clinical study sponsors). Also, the level of trust in the medical profession can play a part in the recruitment process. Research indicates those of ethnic or religious minorities may question why they are being asked to participate in clinical studies. This can be exacerbated if the language we choose to communicate with is different from a participant's first language. Everything we do should help build trust between minority communities and research institution/clinical study organisers. Transparency, honesty and clarity are key to this endeavour.

RECOMMENDATIONS:

Use short sentences where possible to aid understanding. **This is particularly important when communicating with subjects whose first language is not English**

State the ethical standards under which the study has been devised. **For example, state an institutional review board approval has been granted, where known**

State clinical study identification number **(NCT and/or EudraCT number), if known**

Investigational and other drugs

Religious beliefs may prevent potential participants from entering in a clinical study if they are made aware that the investigational product, its non-active ingredients, or other products required under the protocol, are derived from or contain animal material. As explained in figure 2.

Faith	Pigs	Cows	Human
Hinduism	✗	✗	
Sikhism	✗	✗	
Islam (Sunni and Shiite)	✗		
Christian (Catholic, Protestant, African indigenous and Jehovah)			
Judaism			
Buddhist			

Figure 2: Product derivations permitted during clinical studies

However, the use of these products is allowed if no alternatives are available or if used in an emergency. It is worth noting the use of porcine or bovine sources for drug production is in decline, but the use of other animal and human cell sources is becoming more prevalent as more biologic drugs are being developed.

Products that are derived from blood or primary blood components may be unacceptable to Jehovah's Witnesses.

RECOMMENDATIONS:

If an investigational drug contains materials from one of the non-permissible animal sources then we cannot hide this fact from participants. This also applies to non-active ingredients, and any other products or devices to be given to a clinical study participant. It should be clearly stated in recruitment materials. It is better to be transparent from the outset than to have a participant find out after entering the study.

Subject rights and confidentiality

It is accepted that patients must feel they are in control of their care, whether participating in a clinical study or not, which includes confidentiality. All clinical study protocols have a confidentiality statement. It is usual practice for a participant to be assigned a unique identifier, and any participant records or datasets transferred to the study sponsor will contain the identifier only. Participant name or any information which would make the participant identifiable is not transferred.

Many of us assume that confidentiality, particularly in matters of health, is a basic right even if we then choose to allow some information about us to be released under given circumstances. The Muslim faith goes further by mandating confidentiality under Islamic law. We should be clear with those considering entering a clinical research study that confidentiality is integral to the study process. Under certain circumstances, some data about a participant may be released to those outside the research site. We should be clear to state these circumstances too.

The right to privacy is not just related to information about us. It can also be associated with modesty. For example, Muslim, Sikh and Hindu women prefer to see female medical professionals, and the fear they may be examined by a male doctor could be enough to put them off considering clinical study participation.

RECOMMENDATIONS:

State in recruitment materials that confidentiality is assured and outline how that occurs e.g. unique identifier

State under what circumstances confidential data may be released and to whom. This will usually be explicit in the informed consent documentation

If physical examination is a requirement in the study then it may be worth considering adding copy to reflect that female healthcare professionals will be available to carry out examinations

Consent to participate

Participants must sign a consent form to enter a research study. This can sometimes be called a Consent to Participate in a Research Study, or an Informed Consent, or an Information and Assent Form. When communicating in a language that is different from the participant's first language, it may be difficult for them to fully understand the meaning and implications of the consent they are granting.

RECOMMENDATIONS:

- **Use simple language and short sentences where possible**
- **Use pictures, diagrams and icons to illustrate and support copy**
- **Avoid using the term clinical 'trial' but rather use 'study'**

Recompense for participation

If a potential recruit thinks they will have to pay to participate this presents a barrier. Most studies will state that costs for study related treatments, procedures, and reasonable expenses incurred by the participant will be paid by the study sponsor.

Receiving of expenses does not appear to be prohibited on religious or ethnic grounds.

RECOMMENDATIONS:

- **If it is clear from the protocol or consent documentation that costs for study related treatments, procedures, and reasonable expenses will be paid, then include this in your copy**

Risks and benefits of participation

There are risks associated with participating in any clinical research study and fear of the unknown is a major barrier to study participation. But there are also risks from diseases and drugs licensed to treat such conditions. We should not minimise or emphasize these risks, but set them into context.

The risk of taking a drug that may give rise to side effects affecting cognitive function are likely to be unwelcome to the Buddhist community for whom clarity of mind is important. But transparency and openness in your communication will do much to allay these concerns.

The Islamic faith does not preclude participation in clinical studies. Indeed, it supports such work because principles of Islamic teaching are to secure benefits for people, and protection from harm. Even though an individual participant may derive no benefit from a study, this is allowed because of the wider benefit to society.

RECOMMENDATIONS:

Follow the informed consent documentation closely.
This usually sets risks into context with greater clarity for the participant than the more scientifically orientated protocol

Be clear that a participant may or may not derive benefit themselves from entering a clinical study. Their condition may get better, may stay the same or get worse. But their participation may help others with the same condition in the future

The concept of altruism, helping others, benefiting society, or successes in developing medicines for conditions previously untreatable, can be powerful facilitators to study participation and should be supported in recruitment materials

Access to information

Here at COUCH Health Communications we can help by making the copy, and design, more accessible. It's worth remembering that in some cultures, for example, African Caribbean, they find it difficult to discuss ill health with strangers, including members of the medical community.

Research has shown a lack of information is seen as a barrier to study participation. We should seek to provide as much information as we believe it is necessary across our materials to inform and answer questions.

RECOMMENDATIONS:

In addition to using simple language as described earlier, we should provide as much information as is necessary to enable the potential participant to understand the study and their role in it. In some cases, repeating what one would normally expect a study doctor to say

Ethical principles in clinical studies

Given the well documented distrust and fear expressed in reference sources by those considering entering clinical studies, there is a clear need to communicate the ethical standards under which a study is conducted. Some study protocols and consent forms will state these ethical standards. These are some examples:

I. Derived from international guidelines including Declaration of Helsinki and the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines.

II. Applicable International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines.

III. Applicable laws and regulations.

RECOMMENDATIONS:

Ethical standards should be included in communications. There's no need to over burden the copy, but be sure to inform the reader of the importance we place on ethical standards

An Institutional review board/independent ethics committee will have approved the study, so do add that to your copy

Further reading

For those who wish to read more on the subject, these references are recommended.

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- The Handbook of Faiths and Cultures. Respecting the Religious and Cultural needs of patients. Online resource. (https://www.gmmh.nhs.uk/download.cfm?doc=docm93jijm4n901)

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