Use of external platform for recruitment

External companies such as Ionis Call Center, TrialTech, Tricals, Clariness,... serve as online platforms ("call centers") that assist in the recruitment of participants for specific studies. These companies promote the study through various digital channels, including social media. Interested individuals—whether potential participants, their family members, or healthcare professionals—can reach out to these organizations to obtain more information about the trial. During this interaction, certain personal details may be collected to conduct an initial prescreening. Eligible candidates may then be referred to participating research sites, and/or their contact information may be shared directly with the relevant sites.

While the use of such call centers may provide certain advantages in terms of accessibility and workload management, UZ Leuven is concerned about the broader implications of this approach. The use of recruitment platforms raises several important issues that warrant attention. Key concerns related to this type of outsourcing include:

1. **Privacy**: When external companies are involved in the recruitment process, the privacy of potential participants may not always be guaranteed. In some cases, data such as the language and location of potential participants may be shared with the sponsor. According to GCP guidelines [1], the identity of the participant must remain protected from the sponsor at all times. Furthermore, data retention periods can vary, and collected data are not always destroyed immediately. It is essential that potential participants are clearly informed about the nature of this data collection and provide their explicit consent. Additionally, participants should have the option to withdraw their consent at any time.
2. **Patient Perception and Trust**: Patients may feel that they are not adequately followed up or that they have no personal contact after enrolling in a study. This can undermine their trust in the care provided and in the medical teams. As a result, participants are likely to exhibit reduced compliance due to a lack of connection. It is preferable for patients to contact the study team at the relevant site directly, allowing for communication with the treating healthcare providers.
3. **Patient Loss**: There is a risk that patients who sign up for a study through a call center may be referred to another site than UZ Leuven, despite ongoing care at UZ Leuven. This could not only be detrimental to the patient but also disrupt the continuity of care.
4. **Training and Language Barriers**: Call center staff may lack the necessary medical training, raising concerns about their ability to provide accurate information. Additionally, the language of communication is sometimes limited to English, which could create communication challenges for non-English-speaking patients.

UZ Leuven therefore strongly advises against the use of external companies for patient recruitment. Instead, initial contact with potential participants should be conducted by a member of the treating team, with the recruitment organized within the hospital context.

Given the concerns about decentralized recruitment, physicians at UZ Leuven are also requested to actively inform patients about the existence and potential risks of external recruitment platforms. They are strongly encouraged to advise patients against engaging

through these external channels and to instead always consult their treating physician first before taking further steps. In addition, on initial contact, the call centre should ask whether the potential participant is already a patient in a hospital participating as site in the study. If so, this person should be referred to that hospital for participation. In principle, when dealing with patients already under treatment at UZ Leuven, recruitment should be conducted by the UZ Leuven researcher. The use of an external call center is permitted solely if the study team can provide a valid justification—such as challenges in recruitment. This initiative must originate from the principal investigator or study team and comply with the conditions outlined.

However, some platforms do not perform actual prescreening but serve solely as intermediaries or communication hubs, often focusing on specific rare pathologies. It is important to distinguish between ‘recruitment’ and ‘prescreening’. In both cases, the consent of the potential participant is required. However, if study-specific data are already being collected, as is typical during a prescreening, an Informed Consent Form must be administered and signed.

Additionally, it is important to distinguish between the recruitment of patients and healthy volunteers, as the primary concerns associated with these platforms generally do not apply to the recruitment of healthy volunteers.

Furthermore, it should be discussed with each site whether or not they want to work with the platform.

It can be concluded that significant caution surrounds the use of external recruitment, and that its application is only allowed under specific circumstances. Moreover, in those specific cases, the following conditions should be met at all times:

1. **Data minimization**: Only basic contact information may be processed, and no (sensitive) medical data should be collected.
2. **Participant privacy**: Participant data must be stored securely, with confidentiality maintained and a defined retention period.
3. **Added value**: The call center’s role must be justified. The added value of the intermediary must be clear.
4. **Staff training**: Call center staff must have sufficient medical knowledge to provide accurate information and prevent misunderstandings.
5. **Language proficiency**: Call center staff must speak the participant’s language to ensure clear and accurate communication.

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[1] GCP 1.58 Trial Participant Identification Code: A unique identifier assigned to each trial participant to protect the participant’s identity and used in lieu of the participant’s name when the investigator reports adverse events and/or other trial-related data.
