avoiding loss of medical information during clinical investigations

Written by R. Gruber
Avoiding Loss of Medical Information During Clinical Investigations

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One of the challenges in conducting clinical investigations of medical devices is obtaining reliable data. This article outlines some issues to consider to help achieve this.

A basic consideration
This article addresses one of the major practical elements of conducting clinical investigations on medical devices: language and terminology. It is essential to identify possible differences in wording in the study protocol, in ISO 14155, Clinical Investigation of Medical Devices for Human Subjects, in the clinical research organisation’s standard operating procedures and in current medical language, to minimise loss of patient- or device-related information.

Filling in a case report form (CRF), entering data into a database and evaluating the acquired data requires the creation of an image of the medical condition and the health status of a patient. Principally, the CRF and its projection, that is, the database that is collated, are a kind of raster “grid.” Precision in the reality that is outlined in the data set depends on the width of this grid, that is, the scope of data gathered in it. Just as in digital photography where high-resolution images are more expensive, the wider (finer) the grid, the more profound and expensive to acquire are the clinical data. The degree of acceptable precision of the clinical data in a clinical investigation will usually be predefined by the sponsor according to the regulatory needs as well as safety and efficacy related considerations.

Problems of precision
Sources of imprecision are not only confined to the chosen gridwidth. Medical and social information is transported in professional language and numbers. Most professional “slang” is unsystematic and implicit. Many professional terms are specific only within their discipline of origin. This is why terms like this should be identified prior to a trial to minimise information loss. Once ambiguous terms have been identified, they should be uniquely identified by adding an extension or redefinition. The doctor’s way of thinking is to start with the identification of a symptom, to arrive at a diagnosis and then to define treatment. Symptoms without any firm diagnosis allow physicians to take short cuts to symptomatic treatments, thereby skipping diagnosis. Some terms that are strictly symptoms are established as diagnoses in everyday language: she/he has got a fever, oedema, rash, itching, dyspnoea, backache and so forth. During the course of a clinical trial, this type of imprecision in medical wording can create problems.

For example, a doctor may say the following about a patient: “… nice old guy, top fit, 1950 a working accident with loss of the right hand, had pneumonia last winter, and gangrene of one of the toes. His prostate is one of his main problems, he once had an acute LUTS, post TUR-P now (see Table I for definitions), no problems beyond...
sight incontinency when he’s coughing or travelling uphill in his wheelchair, which he needs for his bad spine ...

He’s always got cold feet, got to get the interventional radiologist to work on that again once the prosthesis for the hand fits well, but we’ll have to revise the amputation site once more, just a small correction. Right now, his temp. went up a little bit and he’s got 17000 leukos, it’ll probably be the lungs again, but all right, no dyspnoea, fully compensated, I’ll have him X-rayed at 3 pm, gave him some antibiotics already …

**Term definitions, term separations and terminology**

What makes clinical-trial monitoring such a difficult task is the content of information. The text above provides information not only about the patient, but also about the physician. The latter is one of those nice competent doctors who wears a stethoscope around his neck; he knows his patients well and has lots of time and compassion. As for the old gentleman in the example, everyone has come across an old gentleman like this one; it almost conjures up memories of grandad’s. As for the reader’s stored information, transmitted information, but from the reader’s mind of the reader results not from the reader’s stored information. The text above provides a great deal of what comes into the reader’s mind; the reader interprets it using his/her personal set of life experiences. A great deal of what comes into the mind of the reader results not from transmitted information, but from the reader’s stored information.

Because speaker and listener/writer and reader have similar sets of experiences, language works rather well. However, a database has no access to implicit content.

A look at the old gentleman’s health condition can help clarify what happens to his medical history after it passes into a clinical trial’s database. Table I illustrates how the original information may be stored in the doctor’s mind. The doctor’s written report is based on different subsets of the information available in his “term-separation matrix.” A term-separation matrix for clinical studies reflects the way in which information of the same type is stored in a database. This matrix has a different set of terms because of the need to use coding systems and current abbreviations imposed by the International Conference on Harmonisation (www.ich.org) and the fact that the time frame for “previous” and “concomitant” can be arbitrarily defined by sponsors; for example, these can be established merely as “one year prior to inclusion” when there is a need to take previous medical history events into consideration.

The examples in Table II show the importance of understanding the need to systematically structure the available medical and social information; this will lead to some redundancy of information. Within the context of different terminologies encountered during a clinical trial, some seemingly redundant data have to be included …

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**Table I:** Physician’s terminology.

<table>
<thead>
<tr>
<th>Symptom at time point X</th>
<th>Diagnosis</th>
<th>Therapy</th>
<th>Anamnesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can be measured, ausculted, seen at time point X</td>
<td>Is the fundamental pathological principle in vigour at time point X</td>
<td>Can be performed against the diagnosis or the symptom, starting at time point X</td>
<td>List of relevant diagnoses and consecutive relevant conditions</td>
</tr>
<tr>
<td>Fever, cough, dyspnoea</td>
<td>Susp. pneumonia</td>
<td>Antibiotics, respirator</td>
<td>Stp pneumonia</td>
</tr>
<tr>
<td>Missing hand</td>
<td>Stp traumatic amputation</td>
<td>Prosthesis</td>
<td>Stp amputation left hand due to trauma</td>
</tr>
<tr>
<td>Black toe</td>
<td>PAOD, A. poplitea, gangrene D1 right toe</td>
<td>Amputation D1 right foot, balloon dilation of popliteal artery</td>
<td>PAOD, stp balloon dilation; amputation D1 right foot for gangrene</td>
</tr>
<tr>
<td>Bent back, X-rays show massive degenerative changes</td>
<td>Morbus Bechterew</td>
<td>Physiotherapy, corset, analgetics, wheelchair</td>
<td>Restricted to wheelchair due to Morbus Bechterew</td>
</tr>
<tr>
<td>Massive lower abdominal pains, urine retention</td>
<td>Massive BPH with LUTS, pre-op.</td>
<td>Suprapubic catheter, TUR-P</td>
<td>Stp TUR-P for LUTS in massive BPH</td>
</tr>
<tr>
<td>17000 leukocytes etc.</td>
<td>Susp. pneumonia</td>
<td>Antibiotics</td>
<td>Pneumonia relapse</td>
</tr>
</tbody>
</table>

**Table II:** Database term-separation matrix.

<table>
<thead>
<tr>
<th>Medical history</th>
<th>Previous operations</th>
<th>Concomitant conditions</th>
<th>Concomitant diseases</th>
<th>Physical examination results</th>
<th>Planned operations</th>
</tr>
</thead>
</table>
| Medical history events into consideration. Than speaker and listener/writer and reader have similar sets of experiences, language works rather well. However, a database has no access to implicit content.

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to minimise loss of information. An example would be pneumonia. This is present under the categories of medical history, previous diseases concomitant diseases and it has to be entered three times into the database to precisely depict the past and present of the patient.

Terms such as “suspicion of” or “status post” must also be retained. They can be considerably important for cohesion controls because they allow a causal medical review of the information stored in the database.

Achieving reliable data
In view of the heterogeneous nature of medical language, and the abbreviations and professional terms that are used worldwide, developing a profound understanding of disease-specific terminology can be a helpful approach to effectively minimising information loss in clinical investigations of medical devices. Examining the slang and the terminology of the trial-related pathologies is an important tactic that will lead to obtaining reliable and cohesive clinical data.

Recommended reading

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