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ClinicalTrials.gov: Linking Patients to Medical Research

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ClinicalTrials.gov is a system designed to provide patients, families, and other members of the public with easy access to Web-based information about clinical research studies. The system owes its creation to a section of the Food and Drug Administration Modernization Act (1997), which charged the National Institutes of Health (NIH) with creating such a resource. The scope of this legislation is broad, requiring publicly available information on all clinical trials—whether federally or privately funded—for experimental treatments for serious or life-threatening diseases and conditions. On behalf of all NIH Institutes, the National Library of Medicine (NLM) developed *ClinicalTrials.gov* and made it available to the public in February 2000.

There are currently over 5,700 records in the database, representing primarily NIH-sponsored trials, though trials from other federal agencies and the private sector are increasingly being included. Each record in the database includes a summary of the purpose of the trial, its recruiting status, the criteria for patient participation, the location of the trial, and specific contact information. An important feature of the database is its "just-in-time" access to other online health resources, such as NLM's MEDLINE and MEDLINE*plus*. These resources help place clinical trials in the context of a patient's overall medical care. Figure 22.1 shows a sample search for "leukemia" and "bone marrow transplant."

Figure 22.2 shows the result of the search. Before clicking on any specific record, the user can easily see not only which trials are currently recruiting patients, but also which conditions those trials are studying. Once users choose a trial record, they may click on a link to related information available through NLM's consumer health site, MEDLINE*plus*. Figure 22.3 illustrates this capability. As illustrated in Figure 22.4, users can access additional information for the trial, including links to MEDLINE references, through NLM's PubMed system. Underlying the public Web site of *ClinicalTrials.gov* is a system designed to receive, process, validate, manage, and maintain data from a large number of sources (McCray & Ide, 2000; McCray, 2000). We use the knowledge represented in the NLM's

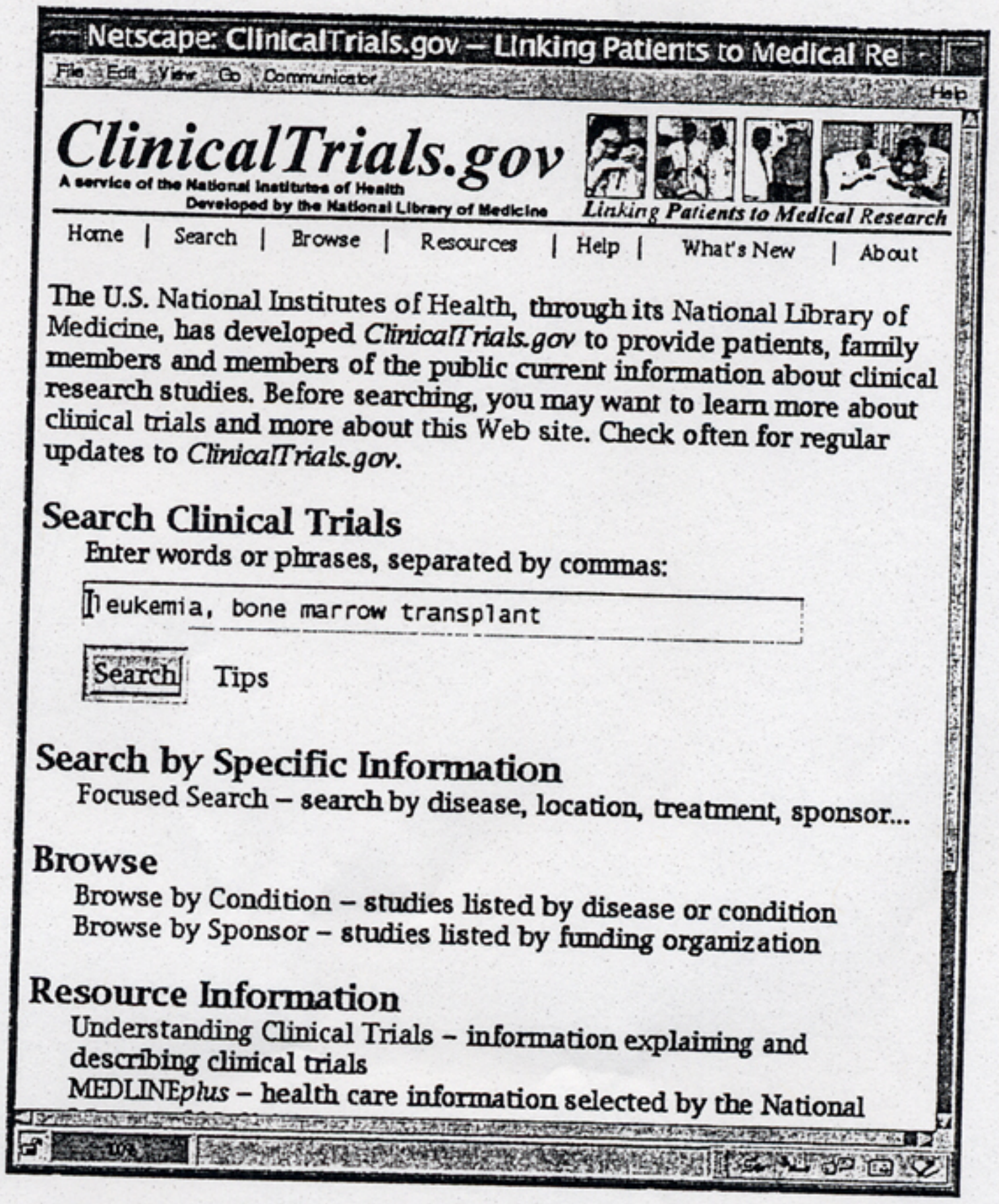

FIGURE 22.1. Simple search on *ClinicalTrials.gov* home page.

Unified Medical Language System (UMLS) Knowledge Sources (http://umlsinfo.nlm.nih.gov/) to ensure flexible access to the data. For example, we transform searches by adding UMLS synonyms to users' queries, and we create browsable condition name lists by mapping the disease terms found in our records to UMLS concepts.

For encoding the data, we have developed a standard set of data elements submitted to us according to an XML (eXtensible Markup Language) DTD (Document Type Definition). This standard set of data elements helps ensure that coverage and presentation are uniform, despite many different data providers. Deliberations about the optimal set of elements were informed by earlier work conducted at the NIH and elsewhere (Meinert, 1988; Spilker, 1996; International Collaborative Group on Clinical Trial Registries, 1993; International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996).

Table 22.1 shows a summary of the data elements.

ClinicalTrials.gov has been available to the public for approximately one and a half years. During that time, the number of visits to the site has

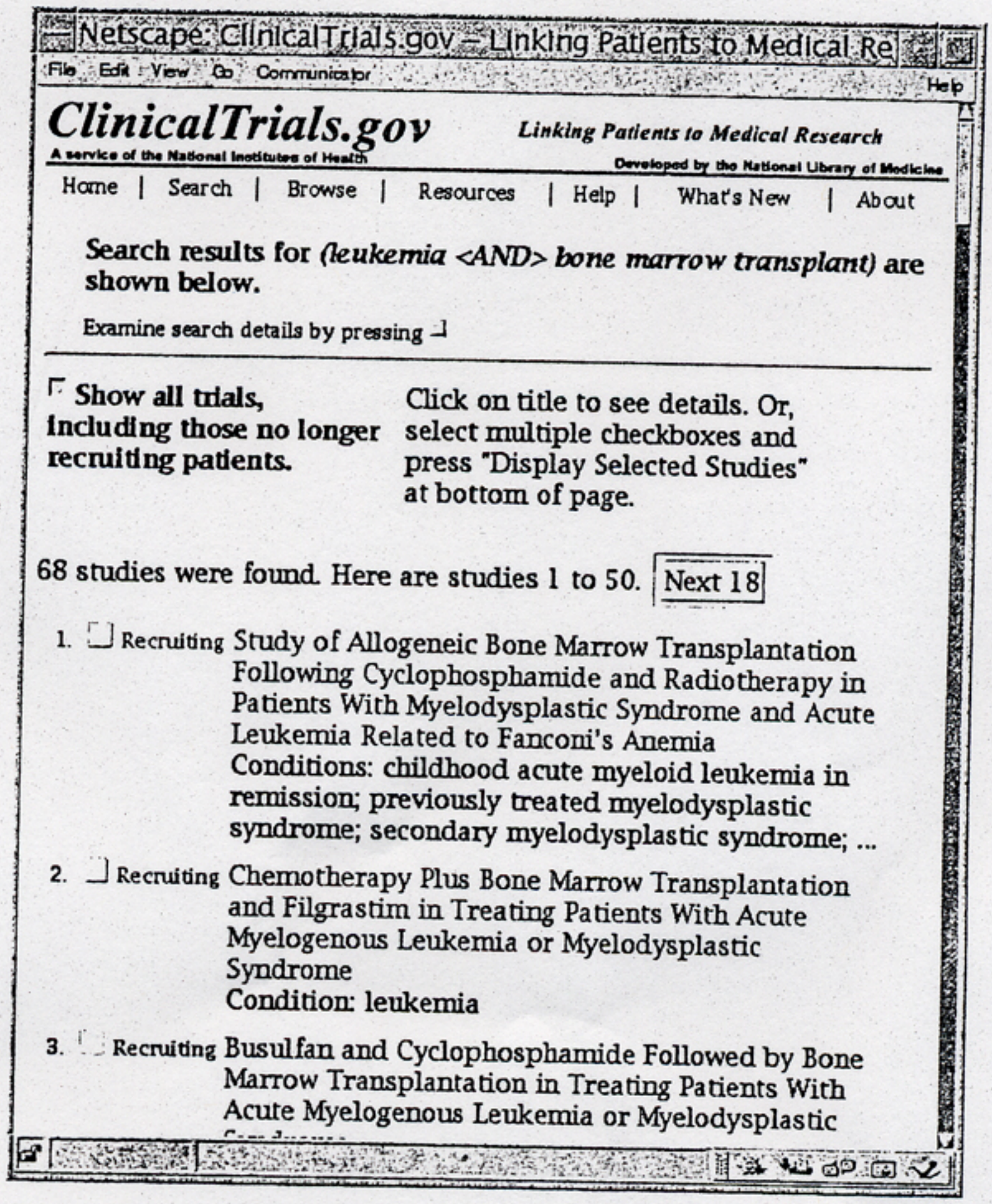

FIGURE 22.2. Search results for a simple search on *ClinicalTrials.gov*.

exceeded 33 million page hits, representing more than 5,000 individual users each day. As we add more trials from other federal agencies and the private sector, and as our broad base of users requests additional capabilities, the system will continue to grow in both coverage and functionality.

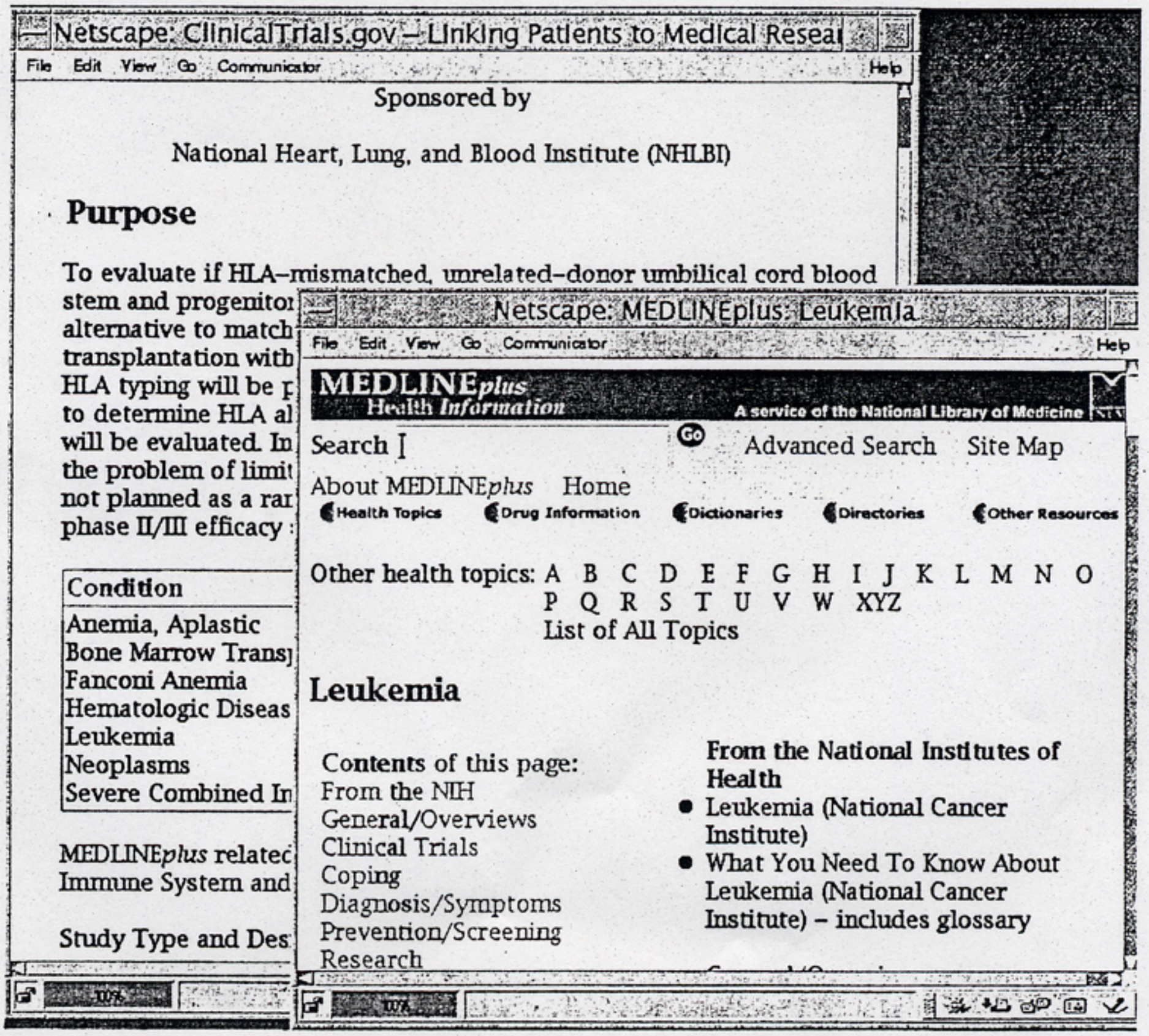

FIGURE 22.3. Portion of a *ClinicalTrials.gov* record with links to MEDLINE*plus*.

References

FDA Modernization Act of 1997, Public Law 105–115, Section 113. Information Program on Clinical Trials for Serious or Life-Threatening Diseases. http://www.fda.gov/cder/guidance/105-115.htm. Accessed 12/20/2000.

International Collaborative Group on Clinical Trial Registries. 1993. Position Paper and Consensus Recommendations on Clinical Trial Registries. Clinical Trials Metaanalysis 28:255–266.

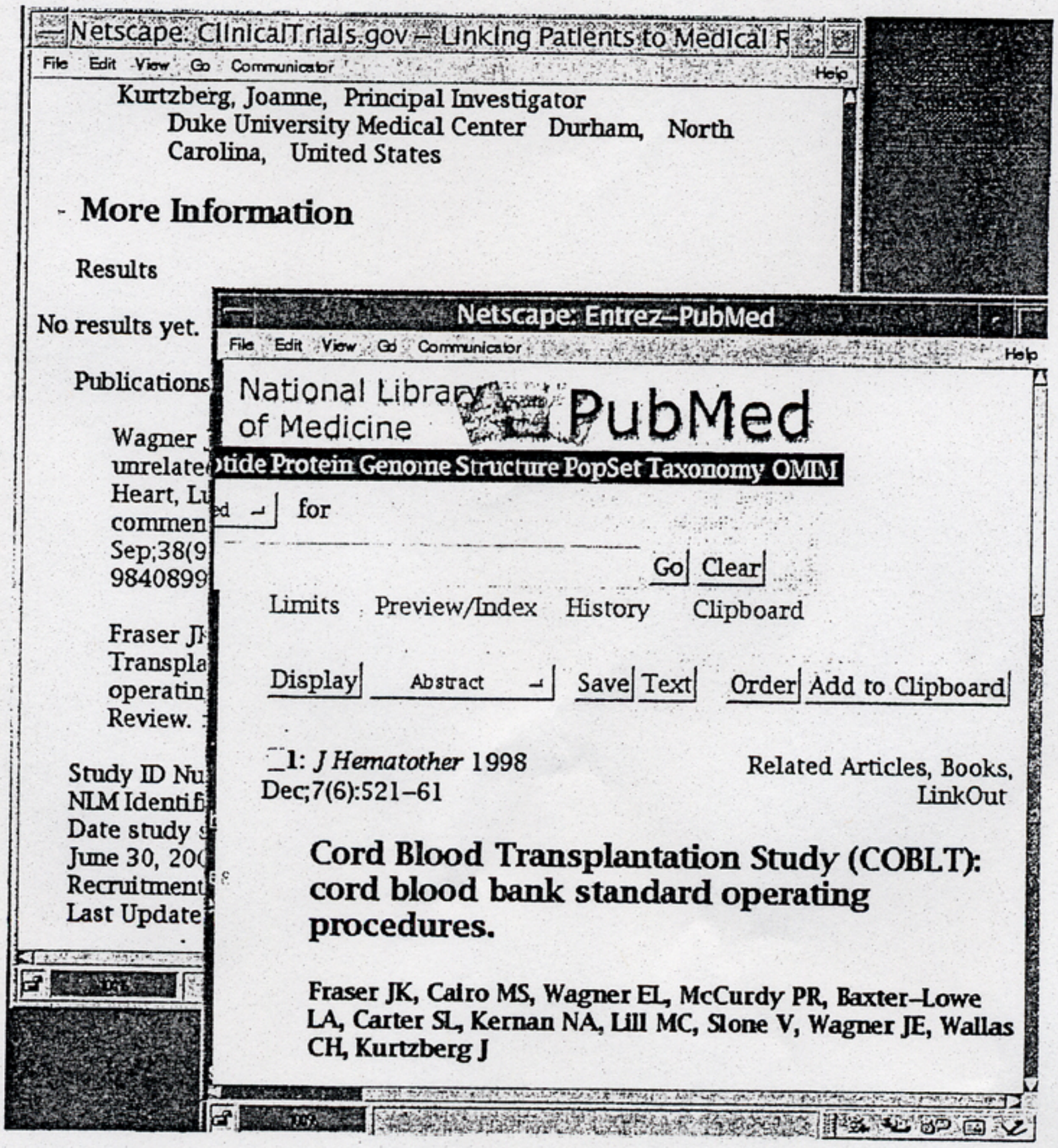

FIGURE 22.4. Portion of a *ClinicalTrials.gov* record with links to PubMed.

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. 1996. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice, 30–33. http://www.ifpma.org/pdfifpma/e6.pdf. Accessed 12/20/2000.

McCray AT, Ide NC. 2000. Design and Implementation of a National Clinical Trials Registry. Journal of the American Medical Informatics Association 7(3):313–323.

Table 22.1. Summary of data elements in *ClinicalTrials.gov*

Data Elements	Description
Unique identifier	Primary unique identifier assigned by the sponsoring organization; any secondary identifiers assigned by other groups
Title	Brief protocol title intended for the public; additional official title provided by the principal investigator, if desired
Sponsor information	Name of sponsoring organizations that initiate and take responsibility for the clinical investigation; information related to sponsor's Food and Drug Administration Investigational New Drug (IND) application
Study description	Brief summary describing the purpose of the trial intended for use by patients; detailed description, giving a technical summary for health professionals
Study status	Phase of the study investigation; type of investigation (e.g., interventional or observational); recruiting status (e.g., not yet recruiting, recruiting, completed); study start and stop dates
Study design	Primary investigative techniques used in the protocol, including reason for the protocol (e.g., treatment, prevention), allocation of subjects (e.g., randomization), masking (e.g., double blind), control (e.g., dose comparison), intervention assignments (e.g., cross-over), study endpoints.
Interventions	Intervention type (e.g., drug, vaccine, device); intervention name (using NLM's Medical Subject Headings if possible)
Conditions	Primary diseases or conditions being studied (using NLM's Medical Subject Headings)
Keywords	Additional important terms for search purposes (using NLM's Medical Subject Headings)
Eligibility criteria	Summary of specific criteria for subject selection, including age and gender
Location and contact information	Name and location of each facility where the trial is being conducted; name and phone number of a contact individual at each location; investigator information
Related information	Citations to published articles related to the protocol; pointers to Web sites that are relevant to the trial

McCray AT. 2000. Better Access to Information about Clinical Trials. Annals of Internal Medicine 133(8):609–614.

Meinert CL. 1988. Toward Prospective Registration of Clinical Trials. Controlled Clinical Trials 9:1–5.

Spilker B. 1996. Guide to Clinical Trials. Philadelphia: Lippincott-Raven. 816–819.

UMLS Information. http://umlsinfo.nlm.nih.gov/. Accessed 12/20/2000.