User Profiles - NCI

Some significant examples of collaborations and use of EVS resources and services are briefly outlined in this section covering NCI, and in later sections covering NIH, government and standards organizations, and other organizations in the cancer research and biomedical community. This section includes the following NCI profiles:

NCI Division of Cancer Biology (DCB)

EVS has supported DCB research on mouse and other animal models of cancer for more than 10 years. EVS has helped develop and maintain accurate coding and classification terminology for animal models, and has worked with NCI and community partners to develop accurate mappings between terminologies currently in use. Key NCI components of this effort are described here, while community partners are described later 14 - User Profiles - Broader Community.

Mouse Models of Human Cancer Consortium (MMHCC) was established by NCI in 1999 to accelerate the development and validation of mouse models by the scientific community. When the MMHCC was initiated, one of the early projects was to create a repository of curated information about animal models that have been employed in cancer studies, called the **Cancer Models Database** (now **caMOD**). EVS staff participated in developing the classifications of mouse diagnoses used for annotating the mouse models, and provided support for additional terminology such as strains and anatomy. All of this terminology has been incorporated into NCI Thesaurus (NCIt), used by caMOD and other users through both browser and programming interfaces. caMOD annotates information with NCIt terminology, and uses the LexEVS API directly to generate anatomy and diagnosis tree hierarchies. 400 concepts were added or updated for caMOD in the last-recorded six month period.

EVS has supported periodic updates to this animal model terminology, and has extended terminology support to cover rats and zebrafish, using existing community standards where available:

- **International Harmonization of Rat Nomenclature (RENI)** was used as the foundation for the Terminology of Rat Pathologic Diagnoses in NCI Thesaurus (NCIt).
- **Zebrafish Information Network (ZFIN)** zebrafish anatomy is provided as a standalone terminology in EVS systems including the NCI Term Browser.

MMHCC has merged with the **Mouse Repository at Frederick National Research Laboratories**, which provides mouse cancer models and associated strains, live and cryopreserved. Additional future support for updating the diagnosis terminology to reflect new models is anticipated.

For more information, visit the NCI **eMICE** website.

EVS Related References

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NCI Division of Cancer Control and Population Sciences (DCCPS)

DCCPS collaboration includes several terminology projects related to cancer classification, drugs, chemotherapy regimens, and statistics. DCCPS is currently launching a new initiative on standardized terminology for population health data collection.

Portfolio Management Application (PMA-DCCPS): EVS has worked with DCCPS for a number of years to integrate PMA-DCCPS grant coding terminology with other EVS resources. NCIt now includes more than 1,500 concepts for PMA grant coding. PMA terms are also inserted and appear in the NCI Metathesaurus as a separate terminology.

NCI Division of Cancer Prevention (DCP)

DCP has used EVS, and worked consistently with EVS, since 2002, including the following collaborations and uses:

- Use of NCIt agent information in DCP systems.
- Joint work on improved coverage of nutritional and other preventive agents.
- Joint work in wider working groups and other initiatives to harmonize broader NCI agent and adverse event coding practices.

EVS Related References

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NCI DCP and DCTD

EVS staff provides terminology support for the Community Clinical Oncology Program (CCOP), including concepts for use in coding four (4) major clinical trials involving 85,000 patients. An estimated total of 500 studies use NCI Thesaurus terminology.

NCI Division of Cancer Treatment and Diagnosis (DCTD)

Cancer Therapy Evaluation Program (CTEP)

The Cancer Therapy Evaluation Program (CTEP) has had many and sustained collaborations with EVS from 1999 onwards, including:

- Use of NCI Thesaurus (NCIt) terminology for protocol abstraction.
- Harmonization and use of NCIt drug and molecular target information in CTEP systems.
- Harmonization and integration of CTEP disease classification with NCIt, PDQ and MedDRA, involving several detailed comparative mappings and analyses as well as concept based mappings in the NCI Metathesaurus (NCIm).
- Joint development, together with other partners, of the redesigned Common Terminology Criteria for Adverse Events (CTCAE) v.4, which has been widely adopted since its release in 2010 (see the detailed description below).

Common Terminology Criteria for Adverse Events (CTCAE)

CTCAE, created by CTEP in 1983, is used throughout the entire oncology community as the standard classification and severity grading scale for adverse events in cancer therapy clinical trials and other oncology settings. It is also used in a number of non-oncology trials and settings.

Version 4, released in May 2009, is a major update based on extensive international participation by stakeholders and experts. It is harmonized with MedDRA at the Adverse Event (AE) level, includes revised AE terms and severity indicators to reflect clinical effects identified with current oncology interventions, and was selected as a caBIG® vocabulary standard. This version is used by more than 50 academic and research organizations, as well as many commercial and non-profit organizations. Five different Apple applications utilize the NCI Thesaurus version of the CTCAE data, and cite NCIt as the source.

CTCAE is designed to integrate into information networks for safety data exchange, and plays a major role in data management for AE data collection, analysis, and patient outcomes associated with cancer research and care. EVS played a central role in designing and managing this effort, working closely with CTEP, DCP, caBIG®, the FDA, and many participants from the broader community. The revision was developed and deployed using various EVS tools including the BiomedGT Wiki, Protégé editing tools, LexEVS terminology server, NCI Term Browser, and the EVS ftp site .

Cancer Diagnosis Program (CDP) - Diagnostics Evaluation Branch

- EVS is supporting gene nomenclature used in a new CDP Biomarker project, including updating Human Genome Organisation (HUGO) Gene Nomenclature Committee (HGNC) terminology in the EVS servers so it is accessible to CDP curators. See HGNC on NCI Term Browser.
- In an extension to this project, EVS will be creating gene and protein sequence variations in the NCIt, according to HGVS guidelines, for genes /proteins of therapeutic interest as requested by CDP. The initial request is 150 genes (in progress), with about 180 protein variants, 300 gene variants, 300 fusion genes, and 300 fusion proteins.
- This work is to support creation of an application to retrieve content from the NIH Clinical Trial Database into the NCI Clinical Trials Reporting Program (CTRP), and is being done jointly with DCTD, NCI/OCPL, NCI/CCR and NIH/NLM.

EVS Related References

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NCI Division of Extramural Activities (DEA)

DEA is supported by EVS, which helps collect, develop and map grant-related terminology, including representing NCI in the NIH Research, Condition and Disease Categorization (RCDC) effort.

NCI Office of Communications and Public Liaison (OCPL)

OCPL co-managed EVS with CBIIT until late 2007, and has continued as an important partner since that time. Some key areas of ongoing collaboration are:

- **PDQ Terminology** has been used for decades to code cancer clinical trials and other NCI scientific and public information resources, including NCI's Clinical Trials Reporting Program (CTRP) initiative. EVS has used PDQ terminology as a core component of its NCI Thesaurus (NCIt) reference terminology, and has worked to harmonize with and add to PDQ terminology even as NCIt was extended in many ways not required for PDQ itself. EVS took over and carries on efforts to harmonize and cross-link both PDQ terminology and NCIt with other NCI coding terminologies including CTEP disease and adverse event terminologies, NCI Developmental Therapeutics Program drug terms, and terminology from DCCPS and DCP. EVS continues to work with OCPL on strengthening PDQ terminology as a coding and information retrieval resource. See PDQ on NCI Term Browser and the PDQ to NCIt Mapping.

- **NCI Drug Dictionary** provides technical definitions, alternate names, and links to related information for more than 3,000 agents that are being used in the treatment of patients with cancer or cancer-related conditions. Each entry includes a link to a more detailed entry in NCIt, which provides the information presented, as well as links to lists of open and closed cancer clinical trials on NCI's Web site, Cancer.gov. Each month, the NCI Drug Dictionary is used by over 30,000 unique visitors who view more than 65,000 pages.

- **Cancer.gov Database of Cancer Clinical Trials** is updated daily and covers over 11,000 clinical trials now accepting participants, plus more than 25,000 others that are no longer recruiting. NCIt drug terminology is used to index PDQ trials, and EVS has contributed to the development of PDQ Terminology used to code cancers and related conditions, procedures, and chemotherapy regimens.

- **NCI Dictionary of Cancer Terms** defines more than 7,000 cancer and biomedical terms in non-technical language. Terms and definitions are reviewed by a multidisciplinary panel of reviewers, and approximately 50 new and 50 revised terms are included each month. The dictionary is available as a stand-alone resource on every Cancer.gov Web page, and is widely used by other institutions and Web sites. Its contents are integrated into both NCI Thesaurus and NCI Metathesaurus, providing an important resource especially for non-technical users.

EVS Related References

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Other NCI User Profiles

Cooperative Human Tissue Bank (CHTB): EVS has supported terminology creation and editing for this network of research institutions, established by the NCI Cancer Diagnosis Program in 1987 and now including six divisions located at Vanderbilt, U. Penn, UAB School of Medicine, Nationwide Children's Hospital, Ohio State, University of Virginia. CHTB hosts NCI funded tissue facilities and services providing remnant human tissue and fluids from routine procedures to investigators. There is active use by 14 academic and research organizations and eight (8) commercial organizations. EVS staff assisted with matching up terminology used by these groups to NCIt terminology, creating new NCIt concepts and definitions as needed.

Cancer Central Clinical Database (C3D): EVS provides support for C3D, largely through providing the new and updated terminology and definitions for case report forms. C3D currently supports electronic submission of clinical trials data to the NCI Clinical Data System (CDS) and the Clinical Trials Monitoring Service (CTMS/Theradex).

OPEN (Oncology Patient Enrollment Network): This web-based registration system for patient enrollments onto NCI-sponsored Cooperative Group clinical trials is a highly active project; most terminology supplied for this is standard demographic terminology.