

A large, stylized DNA double helix structure is positioned on the left side of the page, rendered in shades of teal and grey. It is surrounded by various molecular models, including spheres and connecting lines, suggesting a scientific or biological theme.

Standard Operating Procedure of Reference Module

SOP 1.4 in iCMDB™

Version 1.1

4-13-2016

CONTENTS

Summary.....	1
Introduction and Purpose	4
Responsibilities.....	4
Specific Procedure	4
Reference	8
External References.....	8
Change History	9

TABLES

Table 1 Summary of SOP in reference module (using PMID 21233402 as example).....	1
Table 2 Categories and description of Reference	4
Table 3 Definition of evidence level	6
Table 4 Definition of super population and population	7

FIGURES

Figure 1 Example of reference entry	3
---	---

SOP of Reference Module

SUMMARY

The standard operating of procedure (SOP) of reference module is summarized in Table 1.

Table 1 Summary of SOP in reference module (using PMID 21233402 as example)

Name	Description/Format	Examples
Article Title*	Title of article in Pubmed. Format should follow Pubmed using sentence case and without any punctuation .	Pretreatment EGFR T790M mutation and BRCA1 mRNA expression in erlotinib-treated advanced non-small-cell lung cancer patients with EGFR mutations
Disease Name	Describe what disease the article focused on if applicable. Possible values are either diseases recorded in database or empty.	NSCLC
Category*	Describe the focus of article based on the seven categories (Table 2). Follow the selection criteria in Table 2.	Article PMID 21233402 described the mutation and drug response and recorded in Genetic Variation module. It was categorized in Mutation Reference .
Author*	First author in abbreviation +space+ et al. (if more than one author). When the article was quoted in ICMDB, the format should be family name of first author + space + et al + English dot + English comma + year .	Rosell R et al. Rosell et al., 2011
Description*	The abstract was used as description.	See Figure 1
Year*	The year that the article was published. Possible value is four-digit number .	2011
Published*	The official abbreviation name of Journal without a full stop if applicable. Otherwise, the name of source is used. Possible values are name of journal, NCCN, FDA, NCI drug, ASCO, ESMO, ClinicalTrials.gov, CFDA.	Clin Cancer Res
PubmedID*	The ID is indicated in Pubmed as PMID if applicable. Otherwise, the doi will be used. If doi is not available, the name of source is used. Possible values are numbers, number in doi format, name of journal, NCCN, FDA, NCI drug, ASCO, ESMO, ClinicalTrials.gov, CFDA.	21233402 doi: 10.1158/1078-0432

*Field are required for every entry.

SOP of Reference Module

Table 1 (continued)

Name	Description/Format	Examples
Evidence level	Categorize the article based on the criteria in Table 3. Possible values are randomized-controlled trial, cohort study, case-control study, case report, animal assay, cell line study.	Case-control study
Link of URL *	The web link of article. Pubmed link is first option.	https://www.ncbi.nlm.nih.gov/pubmed/21233402
Link of file	Upload the file of article	NA
Keywords *	Describe the keywords of the article and separate them by comma.	EGFR, T790M, erotinib, NSCLC
Super population	Categorize the super race of study subjects based on various sets of physical characteristics, mainly genetic ancestry. 5 categories are used including African, American, European, South Asian, East Asian, Others (Table 4)	Example 1: European Example 2: Others
Population	Describe the specific origin/race of study subject if applicable.	Spanish

*Field are required for every entry.

SOP of Reference Module

*Article Title: Pretreatment EGFR T790M mutation and BRCA1 mRNA expression in erlotinib-treated a

Disease Name: Non-Small Cell Lung Cancer Non-Small Cell Lung Cancer

*Category: Mutation Reference *Author: Rosell R et al.

*Description:

PURPOSE:

Advanced non-small-cell lung cancer (NSCLC) patients harboring epidermal growth factor receptor (EGFR) mutations (deletion in exon 19 or L858R) show an impressive progression-free survival of 14 months when treated with erlotinib. However, the presence of EGFR mutations can only imperfectly predict outcome. We hypothesized that progression-free survival could be influenced both by the pretreatment EGFR T790M mutation and by components of DNA repair pathways.

EXPERIMENTAL DESIGN:

We assessed the T790M mutation in pretreatment diagnostic specimens from 129 erlotinib-treated advanced NSCLC patients with EGFR mutations. The expression of eight genes and two proteins involved in DNA repair and four receptor tyrosine kinases was also examined.

RESULTS:

The EGFR T790M mutation was observed in 45 of 129 patients (35%). Progression-free

2368 characters remaining

*Year: 2011 *Published: Clin Cancer Res

Evidence Level: Case Control Study *PubMedID: 21233402

Super Population: Others Population: Spanish

*Link of URL: <http://www.ncbi.nlm.nih.gov/pubmed/21233402> Retrieve

Link of File: + Add...

File Info	Operation
<p>*Keywords: EGFR, T790M, erlotinib, NSCLC</p>	

Figure 1 Example of reference entry

SOP of Reference Module

INTRODUCTION AND PURPOSE

SOP 1.4 is a standard operating procedure to guarantee the accuracy and conciseness of data for reference module in iCMB. The main resources of this module are Pubmed, NCCN, FDA, NCI drug, ASCO, ESMO, ClinicalTrials.gov, CFDA.

The Purpose of SOP 1.4 is to provide detailed guidelines and standards for data search and data entry of reference in reference module.

RESPONSIBILITIES

Whoever creates the record is responsible for the accuracy of the data in reference module.

SPECIFIC PROCEDURE

1. Go to reference module in iCMB database.
2. Click "Add New" hyperlink near "Search" button in the "Search Reference" Page.
3. Record the full official title of the reference using sentence case and without any punctuation.
4. Record the disease name discussed in the reference if applicable (e.g. treatment module). Otherwise, leave it empty. Such situations may occur in pharmacogenetics module, biomarker module, mechanism in genetic variation and disease mutation association module.
5. Select the category based on the focus of the reference. The criteria is described in Table 2.

Table 2 Categories and description of Reference

Type	Description and possible situations
Disease Diagnosis	References discussing disease diagnosis
Lab Method Reference	References introducing lab methodology
Mutation Reference	Genetic Variation module
Treatment Reference	Treatment module
Biomarker Reference	Biomarker module
Disease Reference	Disease module
Drug Reference	The main focus of the reference is about drug. Modules that possibly use this category are: Drug module, Pharmacogenetics module, Virology module

6. Record the first author in the format of "name + initial of family name + 'et al' + dot" if there is more than one author. When referenced to this article in annotation, the format is "(family name + 'et al' + English dot + English comma + year)"



*Author format in reference module: name + initial of family name + 'et al' + English dot
Citation format in annotation: (family name + 'et al' + English dot + English comma + year)*

7. Record the abstract of the reference for "description" in iCMB.
8. Record the published year of reference in number only.

SOP of Reference Module

9. Record the source of reference in “Published”. Possible sources are journal included in Pubmed, NCCN, FDA, NCI drug, ASCO, ESMO, ClinicalTrials.gov, CFDA.
10. Record the PMID in Pubmed for “PubmedID” in iCMBD. Otherwise, the doi is to be recorded. If there is no doi, the name of resource is to be recorded. Possible values are number, number in doi format, NCCN, FDA, NCI drug, ASCO, ESMO, ClinicalTrials.gov, CFDA.
11. Classify the reference based on the study design following the criteria described in Table 3.
12. Record the web link of reference.

i If “Link of URL” is from Pubmed following the format of <http://www.ncbi.nlm.nih.gov/pubmed/nnnnnnnn>, step 3, 6, 7, 8, 9, 10 can be automatically completed by clicking “Retrieve” button. However, please confirm the correctness of information before saving it.

13. Summarize the keywords of the reference separating them by comma and space (e.g. EGFR, T790M).
14. Categorize the super origin of study subjects (African, American, European, South Asian, East Asian and Others) based on the physical characteristics, mainly genetic ancestry. Please use the population code in Table 4, otherwise, type the race mentioned in the article. If the population is not well described in the article, choose others and specify the population name used in the article.

i Please take note that race is different from nationality. Race reflects the physical characteristics, including hair color, skin color, bones, and metabolism and so on, which are determined by genetics. For example, an American could be Caucasian, African and American.

SOP of Reference Module

Table 3 Definition of evidence level

Name	Description	Examples/PMID
Randomized controlled trial (RCT)	A study design that randomly assigns participants into an experimental group or a control group. As the study is conducted, the only expected difference between the control and experimental groups in a RCT is the outcome variable being studied.	17892376
Cohort study	A study design where one or more samples (called cohorts) are followed prospectively and subsequent status evaluations with respect to a disease or outcome are conducted to determine which initial participants exposure characteristics (risk factors) are associated with it. As the study is conducted, outcome from participants in each cohort is measured and relationships with specific characteristics determined.	17901448
Case-control study	<p>Study that compares patients who have a disease or outcome of interest (cases) with patients who do not have the disease or outcome (controls), and looks back retrospectively to compare how frequently the exposure to a risk factor is present in each group to determine the relationship between the risk factor and the disease.</p> <p>Case control studies are observational because no intervention is attempted and no attempt is made to alter the course of the disease.</p>	16467545
Case report	Description and interpretation of an individual case. It is often written in the form of a detailed story.	12737865
Animal assay	Study conducted in animal model	25730907
Cell line study	In vitro study conducted in cell line	24983493

SOP of Reference Module

Table 4 Definition of super population and population

Super population	Examples of populations: population (code)
East Asian	Han Chinese in Beijing (CHB); Southern Han Chinese (CHS); Chinese Dai in Xishuangbanna (CDX); Japanese in Tokyo (JPT); Kinh in Ho Chi Minh City, Vietnam (KHV);
South Asian	Gujarati Indian from Houston, Texas (GIH); Punjabi from Lahore, Pakistan (PJL); Bengali from Bangladesh (BEB); Sri Lankan Tamil from the UK (STU); Indian Telugu from the UK (ITU); Singapore; Malay
European	Utah residents with northern and western European(CEU); Toscani in Italia (TSI); Finnish in Finland (FIN); British in England and Scotland (GBR); Iberian Population in Spain (IBS)
African	Yoruba in Ibadan, Nigeria (YRI); Luhya in Webuye, Kenya (LWK); Mandinka in The Gambia (MAG); Mende in Sierra Leone (MSL); Esan in Nigeria (ESN); Americans of African Ancestry in SW USA (ASW); African Caribbeans in Barbados (ACB)
American	Mexican Ancestry from Los Angeles USA (MXL); Puerto Ricans from Puerto Rico (PUR); Colombians from Medellin, Colombia (CLM); Peruvians from Lima, Peru (PEL)

REFERENCE

External References

No.	Resource	Description
1	Pubmed	Pubmed (http://www.ncbi.nlm.nih.gov/pubmed) is National Center for Biotechnology Information (NCBI)'s database for biomedical literature from MEDLINE, life science journals, and online books.
2	NCCN	National Comprehensive Cancer Network (NCCN, http://www.nccn.org/) is an alliance of the world's leading cancer centers. It provides authoritative source of comprehensive cancer care.
3	FDA	Food and Drug Administration (FDA, http://www.fda.gov/) is a federal agency of U.S. It is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. This website updates all related information released by U.S government.
4	NCI drug	National Cancer Institute drug dictionary (NCI drug, http://www.cancer.gov/publications/dictionaries/cancer-drug) is a dictionary where you can search technical definitions and synonyms for drugs/agents used to treat patients with cancer or conditions related to cancer.
5	ASCO	American Society of Clinical Oncology (ASCO, http://www.asco.org/) is a professional organization representing physicians of all oncology subspecialties who care for people with cancer. This website updates new findings or recommendations in oncology.
6	ESMO	European Society of Medical Oncology (ESMO, http://www.esmo.org/) is a non-profit professional medical oncology society in Europe. It produces evidence-based recommendations for basic standards of cancer care. This website updates new findings or recommendations in oncology.
7	ClinicalTrials.gov	ClinicalTrials.gov (https://www.clinicaltrials.gov/) is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.
8	CFDA	China Food and Drug Admission (CFDA, http://www.sda.gov.cn/WS01/CL0001/) is a Chinese certification authority that is responsible for registration of medical products, medicine, food and cosmetics. This website updates all related information released by China government.
9	Study design 101 tutorials	Study Design 101 (https://himmelfarb.gwu.edu/tutorials/studydesign101/casereports.html) is an online tutorial provided by Himmelfarb Health Sciences Library.
10	FDA race and ethnicity guidance	Collection of Race and Ethnicity Data in Clinical Trials in FDA (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm#f15)

SOP of Reference Module

CHANGE HISTORY

Revision	Date	Significant Changes
0.1	11-Dec-15	Initial version of reference module
1.0	22-Jan-16	First release to department of database
1.1	13-Apr-16	Define categorization for ethnicity of articles -Definition of <i>super population</i> and <i>population</i> in Table 1. -Specific procedure 14 -Table 4

