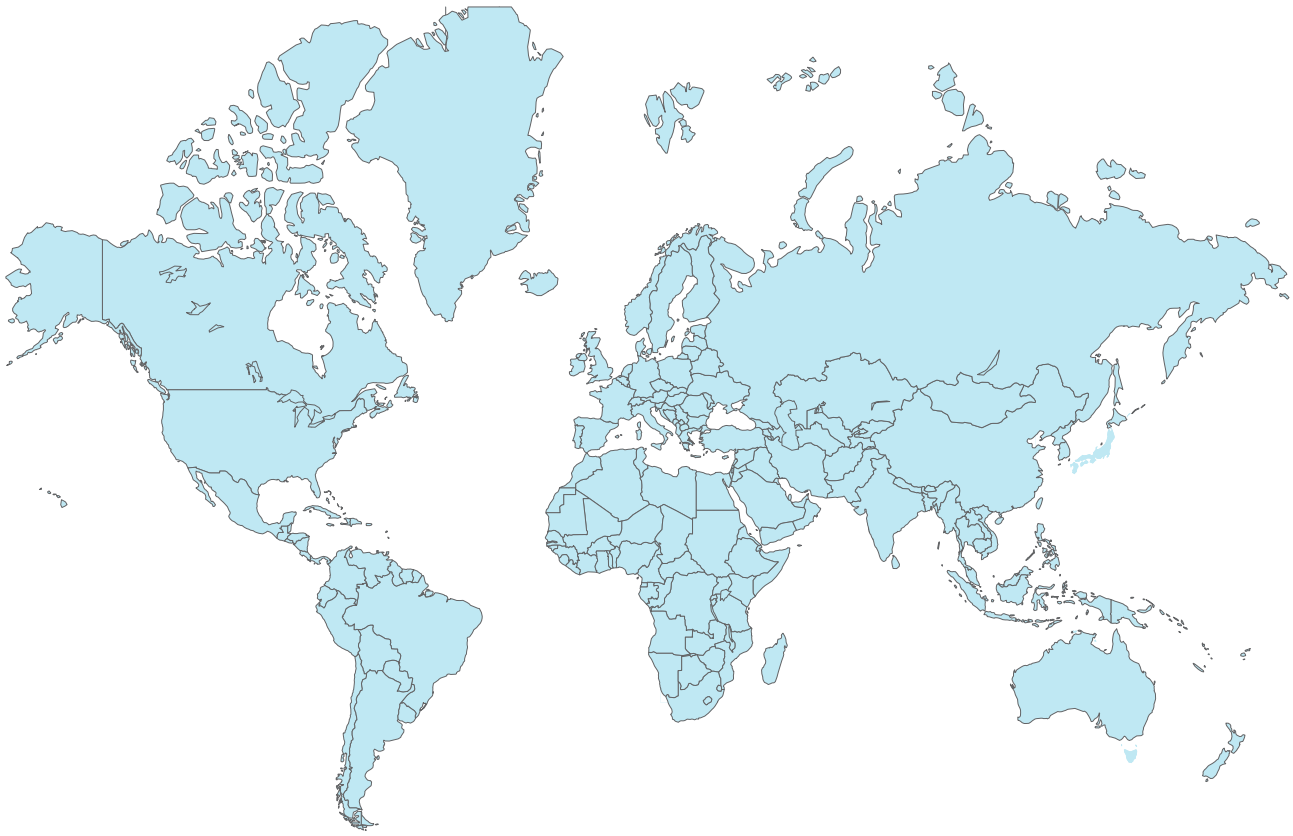
International Cancer
Research Partnership

A methodology for identifying Translational Research

using the Common Scientific Outline (CSO)



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ICRP Partners

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For more information about this report or the ICRP, please contact:

Operations Manager
operations@icrpartnership.org

Contents

Background & Purpose

About the ICRP

The International Cancer Research Partnership's mission is to add value to cancer research efforts internationally by fostering collaboration and strategic co-ordination between cancer research organizations. The vision is that all funders of cancer research collaborate to enhance the impact of research on individuals affected by cancer.

The ICRP is an alliance of governmental and charitable organizations funding regional, national and international cancer research grants and awards. Members of the ICRP submit current and historical research funding information to a common database and share best practices to increase the efficiency of research administration and management. The ICRP database represents a significant portion of the cancer research performed worldwide outside the industrial sector. Key information about ongoing and historical research funding is made available to the public[1] and to the research community. Detailed analysis at the level of individual award finances is available to partner organizations.[2] All cancer research funders are invited to join this initiative.

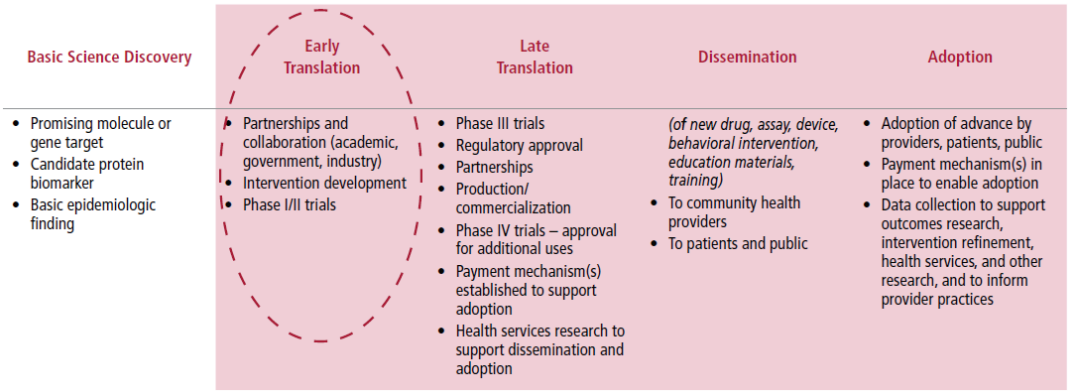
Purpose of this paper

Cancer research organizations worldwide are actively promoting and creating the right conditions for translational research (TR) to flourish, with the aim of accelerating the transition from basic research to clinical testing nd making the latest treatments available for patients. To track progress in promoting and supporting TR, it is important to be able to monitor trends in TR activity.

The term "Translational Research" describes a wide continuum of activities and there have been many differing definitions in circulation over the last few decades, making it difficult to monitor research activity or compare portfolios between research organizations. Strong standards in defining TR have been set by NCI Translational Research Working Group (NCI TRWG)[3], which have also been adopted by the Canadian Cancer Research Alliance (CCRA)[4] and the Dutch Cancer Society (DCS/KWF)[5], with adaptations to serve national and organizational interests. The NCI TRWG conceived of translational research in four main stages that follow basic science discovery and end in adoption/diffusion. The TRWG decided to focus its work on the "early translation" portion of the research translation continuum: "the translational process that follows fundamental discovery and precedes definitive, late-stage trials."

The methodology presented here seeks to complement these TR definitions, using the ICRP's Common Scientific Outline (CSO, Appendix I)as a tool to identify relevant TR awards at the broadest level, so that the workload of applying sub-classifications to awards is reduced.

Figure 1: Translational research schema of the NCI TRWG[3]



1 *https://www.icrpartnership.org/database.cfm*
2 *https://www.icrpartnership.org/Partners/login.cfm*
3 *http://www.cancer.gov/PublishedContent/Files/images/trwg/TRWG_Oct06RT_ExSum_11-21-06.pdf*
4 *http://www.ccra-acrc.ca/index.php/about-us/news-and-announcements/208-investment-in-early-translational-cancer-research*
5 *Personal communication: Dutch Cancer Society (2014).*

Translational Research Methodology

Analysis of ICRP data suggests that awards wholly or partially coded to CSO 3, 4 or 5 can be classed as TR. Patient-oriented TR – research primarily focused on needs in the area of patient care and survivorship (CSO6) - has also been separated out. There is some difficulty in separating out late translation from clinical research, as some CSO codes (e.g., CSO3.3) encompass early and late translational/clinical research. To overcome this a general 'translational' category is also included which encompasses both early and later translation.

Research wholly/partly coded to the following CSO sub-codes[6] is categorized as follows:

Figure 2: CSO - Translational Research coding scheme

CSO	TR category
1.1	-
1.2	-
1.3	-
1.4	-
1.5	-
2.1	-
2.2	-
2.3	-
2.4	-
3.1	Translational
3.2	Translational
3.3	Translational
3.4	Translational
3.5	Translational
3.6	Translational

CSO	TR category
4.1	Translational (early)
4.2	Translational (early)
4.3	Translational/clinical
4.4	Translational
5.1	Translational (early)
5.2	Translational/clinical
5.3	Translational (early)
5.4	Translational/clinical
5.5	Translational/clinical
5.6	Translational/clinical
5.7	Translational

CSO	TR category
6.1	Patient-oriented TR
6.2	Translational
6.3	Patient-oriented TR
6.4	Patient-oriented TR
6.5	Patient-oriented TR
6.6	Patient-oriented TR
6.7	Patient-oriented TR
6.8	Patient-oriented TR *
6.9	Patient-oriented TR
7.1	-*
7.2	-*
7.3	-*

\- Basic research

* Not in CSO v2

So, for example, an award wholly or partially coded to CSO5.4 would be automatically classed to the "Translational/clinical" category and identified as being at the clinical application end of the translational spectrum. Further examples can be see in Figure 3 (right).

Figure 3: CSO-TR examples

An award coded to	Would be automatically classed as
CSO 5.3	Early translational
CSO 5.1 and 2.2	Early translational
CSO 5.4	Translational/clinical
CSO 4.1 and 1.4	Early translational
CSO 6.2 and 2.1	Early translational
CSO 6.1	Patient-oriented TR
CSO 5.4 and 6.4	Translational/clinical (and Patient-oriented)

For detailed analysis, it is possible to be more granular, and apply multiple codes if required to demonstrate that certain awards combine basic, translational and clinical elements. For example, a project Phase III trial of novel therapeutic agent for leukaemia (CSO 5.4) incorporating a translational study to discover biomarkers of response (CSO 4.1), could be classed as both "Early TR" (CSO 4.1) and "TR/Clinical" (CSO 5.4)

6 *The CSO is applied to research portfolios by all ICRP organizations, giving a common framework for analysis and understanding research activity, for further details see Appendix I and visit https://www.icrpartnership.org/CSO.cfm for updates to the system. In 2015, the partners are adopting a new version of the CSO (v2), to address coding ambiguities identified in CSOv1.*

Validation & conclusions

Approach for validating the methodology

Two datasets were used to test a methodology for using the CSO to identify TR:

- KWF awards coded manually to an adapted TRWG system (and also coded to the CSO).
- ICRP bladder cancer awards coded manually to translational research (and also coded to the CSO).

The validation approach taken was to test if automated assignment to TR category using the CSO sub-codes replicated the manual assignment to TR by human coders.

On reviewing the ICRP methodology against the KWF dataset (**Figure 4**, right), the ICRP TR method captured the majority (137/139) of awards classed as TR by manual coders. This was deemed to be an acceptable rate of recall of TR awards. Two projects classed by manual coders as TR were not captured (**Figure 4**, red data points), but as these were coded to CSO 1.2/2.1 and CSO 2.2 respectively, their omission from the ICRP TR coding was felt to be acceptable, as these projects were at the basic end of the TR spectrum. Patient-oriented TR was captured appropriately using the automated methodology.

Similarly, ICRP bladder cancer awards analysed by human coders according to the NCI TRWG schema were also assigned to a TR code using the automated methodology (**Figure 5**, right). Again, the ICRP TR methodology only omitted 2/83 awards (2%) classed as TR by manual coders, which again was felt to be an acceptable rate of recall. As with the KWF dataset, both of the awards coded as TR by manual coders (**Figure 5**, red data points) that were not captured by the automated method were at the basic end of the TR spectrum (CSO2). Including CSO2 codes within the 'translational'

Figure 4: CSO-TR validation using KWF data

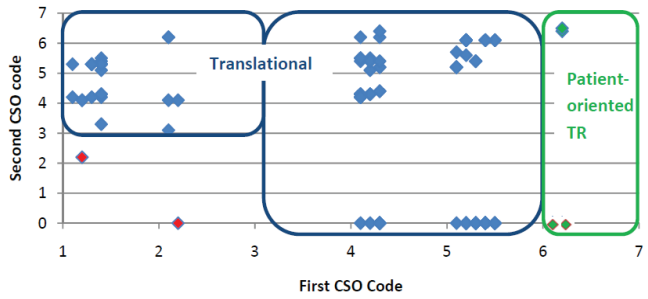
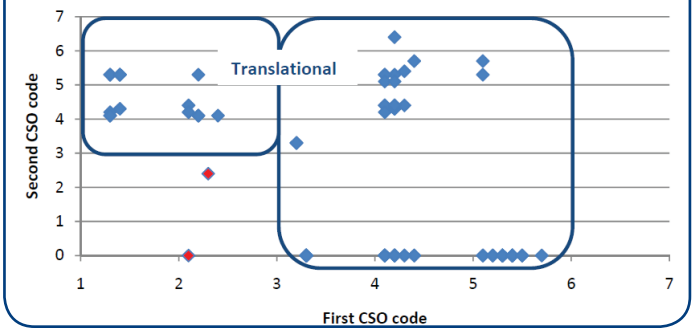


Figure 5: CSO-TR validation using ICRP data



Extension of the approach to the Health Research Classification Scheme

The CSO is closely related to a broad schema for classifying biomedical research - the Health Research Classification Scheme (HRCS)[7] - as the HRCS was developed from the CSO. An extension of this CSO-TR methodology to cover the HRCS is included in Appendix II.

Conclusions

The automated methodology to identify TR described here provides a simple way to track or compare TR activity across portfolios coded to the CSO (or HRCS). In addition, trends in translational research funding can now be identified easily using the existing CSO codes applied to research portfolios. ICRP will use this methodology to monitor trends in TR funding.

7 *http://www.hrcsonline.net/pages/background.*

Description of the CSO

The Common Scientific Outline or 'CSO' is a classification system organized into seven broad areas of scientific interest in cancer research and further divided into sub-categories:

CSO area:	1 - Biology	2 - Etiology	3 - Prevention	4 - Early detection, diagnosis and prognosis	5 - Treatment	6 - Cancer control, survivorship and outcomes	7 - Scientific model systems*
1	Normal functioning	Exogenous Factors in the Origin and Cause of Cancer	Interventions to Prevent Cancer: Personal Behaviors That Affect Cancer Risk	Technology Development and/or Marker Discovery	Localized Therapies – Discovery and Development	Patient Care and Survivorship Issues	Development and Characterization of Model Systems*
2	Cancer Initiation: Alterations in Chromosomes	Endogenous Factors in the Origin and Cause of Cancer	Nutritional Science in Cancer Prevention	Technology and/or Marker Evaluation With Respect to Fundamental Parameters of Method	Localized Therapies: Clinical Applications	Surveillance	Application of Model Systems*
3	Cancer Initiation: Oncogenes and Tumor Suppressor Genes	Interactions of Genes and/ or Genetic Polymorphisms with Exogenous and/or Endogenous Factors	Chemoprevention	Technology and/ or Marker Testing in a Clinical Setting	Systemic Therapies: Discovery and Development	Behavior	Resources and Infrastructure Related to Scientific Model Systems*
4	Cancer Progression and Metastasis	Resources and Infrastructure Related to Etiology	Vaccines	Resources and Infrastructure Related to Detection, Diagnosis, or Prognosis	Systemic Therapies: Clinical Applications	Cost Analyses and Health Care Delivery	--
5	Resources and Infrastructure Related to Biology	--	Complementary and Alternative Prevention Approaches	--	Combinations of Localized and Systemic Therapies	Education and Communication	--
6	--	--	Resources and Infrastructure Related to Prevention	--	Complementary and Alternative Treatment Approaches	End-of-Life Care	--
7	--	--	--	--	Resources and Infrastructure Related to Treatment and the Prevention of Recurrence	Ethics and Confidentiality in Cancer Research	--
8	--	--	--	--	--	Complementary and Alternative Approaches for Supportive Care of Patients and Survivors*	--
9	--	--	--	--	--	Resources and Infrastructure Related to Cancer Control, Survivorship, and Outcomes Research	-

Subcategory

The CSO is complemented by a standard cancer type coding scheme. Full details of the system can be found at https://www.icrpartnership.org/CSO.cfm.

Appendix II

Extension of the methodology to the Health Research Classification System (HRCS)

The HRCS is a system for classifying and analyzing biomedical and health research funding . Its role is to facilitate research management by answering strategic questions about investment. As the HRCS bears a close relation to and was developed from the CSO, the methodology developed above can also be used to identify translational research within HRCS-coded portfolios (including non-cancer biomedical research). However it is important to note that this HRCS methodology has not been extensively tested against HRCS-coded datasets as it has for the CSO.

RA	TR category
1.1	-
1.2	-
1.3	-
1.4	-
1.5	-
2.1	-
2.2	-
2.3	-
2.4	-
2.5	-
2.6	-
3.1	Translational
3.2	Translational
3.3	Translational
3.4	Translational
3.5	Translational

RA	TR category
4.1	Translational (early)
4.2	Translational (early)
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4.4	Translational
4.5	Translational
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5.2	Translational (early)
5.3	Translational (early)
5.4	Translational (early)
5.5	Translational (early)
5.6	Translational (early)
5.7	Translational (early)
5.8	Translational (early)
5.9	Translational (early)
6.1	Translational/clinical
6.2	Translational/clinical

RA	TR category
6.3	Translational/clinical
6.4	Translational/clinical
6.5	Translational/clinical
6.6	Translational/clinical
6.7	Translational/clinical
6.8	Translational/clinical
6.9	Translational/clinical
7.1	Patient-oriented TR
7.2	Patient-oriented TR
7.3	Patient-oriented TR
7.4	Patient-oriented TR
8.1	Patient-oriented TR
8.2	Patient-oriented TR
8.3	Patient-oriented TR
8.4	Patient-oriented TR

- Basic research

Further details about the HRCS can be obtained at: http://www.hrcsonline.net/rac

ICR Partners:

Current members of the ICRP (March 2015)
Over 80 funding organizations and institutes

US

- American Cancer Society
- American Institute for Cancer Research
- Avon Foundation Breast Cancer Crusade
- California Breast Cancer Research Program*
- Congressionally Directed Medical Research Programs, US Department of Defense
- National Institutes of Health (including the National Cancer Institute)
- National Pancreas Foundation
- Oncology Nursing Society Foundation
- Pancreatic Cancer Action Network
- Susan G. Komen®

Australia

- Cancer Australia
- National Breast Cancer Foundation

Canada

- Canadian Cancer Research Alliance *(currently representing 40 funding organizations/programs)*

France

- Institut National du Cancer (French National Cancer Institute) & research co-funded with Direction Générale de l'Offre des Soins (Ministry of Health)

Japan

- National Cancer Center

Netherlands

- KWF Kankerbestrijding (Dutch Cancer Society)

UK

- National Cancer Research Institute *(representing 21 funding organizations)*

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