歐盟癌症轉譯跨國多邊型研究計畫
第 4 次公開徵求計畫書
(TRANSCAN-2-JTC2017)

一、 緣起

歐盟 Horizon 2020 癌症轉譯計畫(**Trans**lational **Can**cer Research – TRANSCAN-2)乃由歐盟研究總署協調歐洲各國整合研發經費，共同投入之跨國癌症轉譯研究計畫，由 TRANSCAN-2 計畫的參與國/機構自行編列研究經費，支應跨國癌症轉譯研究團隊之形成，避免資源重複投資，集各國家所長共同研究。

科技部參與歐盟 TRANSCAN-2 計畫，與歐洲各國同步公開徵求計畫書(詳情請參閱英文版之 **Call Text Document 及 Guidelines for Applicants**，本次為 TRANSCAN-2 第 4 次公開徵求計畫書，本次公開徵求之主題為:

Translational Research on Rare Cancers

二、 申請資格

(一) 公私立大專校院、公立研究機構。
(二) 經科技部認可之財團法人學術研究機構、醫療社團法人學術研究機構。
(三) 計畫主持人需符合「科技部補助專題研究計畫作業要點」規定。

三、 補助經費

本部比照歐盟計畫方案，補助每件獲審查通過之 TRANSCAN-2 研究計畫:

- 補助上限: 新台幣 300 萬/年，
- 計畫期限: 最多不超過 3 年，
- 實際補助金額經本部審查後核定。

四、 補助項目

(一) 國外差旅費(含移地研究費)。

(二) 業務費: 研究人力費(含專任助理、研究生或助理津貼、臨時工資

等）、耗材、物品及雜項費用，及補助國外學者來台費用。

(三) 管理費（上限 8%）。

五、 計畫件數

(一) 比照歐盟計畫辦理: 計畫主持人參與歐盟計畫(3 國以上所組成之跨國研究型計畫)得以 1 件計畫不算件數。

(二) 申請人目前已主持 2 件本部「雙邊協議專案型國際合作研究計畫」，且其計畫執行日期均與本次徵求案之預定執行迄日重疊達 3 個月以上者，得不受理。

六、 TRANSCAN-2 計畫 JTC2017 參與之補助機構

Austrian Science Fund (FWF) Austria
Research Foundation - Flanders (FWO) Belgium
Fund for Scientific Research (FNRS) Belgium French speaking community
Estonian Research Council (ETAg) Estonia
National Cancer Institute (INCa) France
ARC French Foundation for Cancer Research (ARC Foundation) France
Federal Ministry of Education and Research (BMBF) Germany
General Secretariat for Research & Technology (GSRT) Greece*
The Chief Scientist Office in the Ministry of Health (CSO-MOH) Israel
Ministry of Health (MoH) Italy
Alliance Against Cancer (ACC) Italy
Lombardy Foundation for Biomedical Research (FRRB) Italy
State Education Development Agency (VIAA) Latvia
Dutch Cancer Society (DCS) Netherlands
Norwegian Cancer Society (NCS) Norway*
National Centre for Research and Development (NCBR) Poland*
Slovak Academy of Sciences (SAS) Slovakia
Spanish Association Against Cancer Scientific Foundation (FCAECC) Spain
National Institute of Health Carlos III (ISCIII) Spain
The Foundation for the support of the Applied Scientific Research and Technology in Asturias (FICYT) Spain
Ministry of Science and Technology (MoST) Taiwan
Scientific and Technological Research Council (TUBITAK) Turkey

七、 申請方式及運作模式

(一) 本部於 **2017 年 12 月 28 日**公開徵求計畫書。

(二) 我國研究人員欲申請計畫者請自行從參與國中尋求合作夥伴，自行媒合並組成團隊後共同提出申請[1]。獲審查通過推薦之計畫，將由 TRANSCAN-2 計畫參與國/機構自行補助自己國家研究團隊所需之經費，我國之研究團隊/人員所申請或參與之計畫如獲推薦者，則由本部補助所需之研究經費。

請依附件 Pre-Proposal 格式完成構想申請書，於 **2018 年 2 月 6 日前(Central European Time –CET 16:00 前)上傳[2]Pre-proposal 至 TRANSCAN-2 線上計畫申請系統**，並以 Email 方式通知本部陳禹銘博士 (email: ymchen@most.gov.tw)。

http://transcan.cbim.it/

(三) 1 件計畫只需要線上提送 1 份申請書(由多國團隊共同寫 1 份)，故如我國研究人員與歐洲研究人員共同組成 1 隊並由歐洲人員擔任計畫主持人(Coordinator)，則由歐洲計畫主持人(Coordinator)線上一併提出 Pre-Proposal，我方則配合計畫團隊所需提供計畫相關資料；如我國研究人員為計畫主持人(Coordinator)，則必須協調歐洲團隊提供資料，並由我方於指定時間內線上提出申請。

(四) 計畫申請分兩階段審查: 分別為 Pre-Proposal 及 Final Proposal。Pre-Proposal 先經各 TRANSCAN-2 計畫之參與國/機構所組成的審查團隊自行審查 (eligibility check) 後，俟各國 Pre-Proposal 彙齊後，統一委請中立專家審查委員[3]針對各國 Pre-Proposal 進行審查。通過 Pre-Proposal 審查之計畫才會被邀請撰寫 Final Proposal。

(五) Pre-Proposal 於統一彙整後辦理書面審查，1 件計畫平均由至少兩

[1]可於 TRANSCAN 網站(http://www.transcanfp7.eu/)上表達尋求夥伴之需求。
[2]申請一律採線上作業，由 TRANSCAN 網站上繳交送出。
[3]審查委員將由各會員國所推薦之專家學者所組成。

位審查委員[4]審查，審查完畢後會產出計畫優先推薦之排序表，並將於 2018 年 4 月 TRANSCAN-2 Funding Agency 會議討論後決定通過 Pre-Proposal 之件數。

(六) 通過之 Pre-Proposal 將會由 TRANSCAN-2 委員會另行邀請於 2018 年 5 月 30 日**(Central European Summer Time –CEST 16:00)**前，於 TRANSCAN-2 線上計畫申請系統上繳交 Final Proposal。

(七) 每件 Final Proposal 經審查委員審查完畢後，會開放一段時間讓每件計畫主持人評論(答辯)審查委員的意見或回應審查委員的問題(但審查委員所給的分數將不會開放給計畫主持人查閱)。審查委員將會以匿名方式在線上系統呈現。計畫主持人僅能回應審查委員的意見或問題，其餘不相關的部分則不得回應，計畫書內容或工作規劃亦不能再修改或變更，計畫書亦不得再重送。

(八) 如計畫主持人選擇回應審查委員的意見(僅限在 Final Proposal Phase)，必須從 2018 年 8 月 7 日起至 8 月 17 日 16:00 (Central European Summer Time, CEST)前在線上系統內回答。

(九) 通過 Final Proposal 審查[5]獲推薦之計畫將會於 TRANSCAN-2 網站上公告，計畫獲推薦之主持人將會收到正式通知，如我國所參與之計畫經 Final Proposal 審查後獲推薦者，經聯繫本部承辦人後，可至本部學術研發服務網提出申請。

八、 重要日期時間表

下表為 TRANSCAN-2 委員會暫定之時間表，如執行期間有修正，將透過會員國表決通過後，在 TRANSCAN-2 網站上公告更新時程。

Year	Date	Activity
2017	December 5	Launch of the call: JTC-2017 Launch of the national calls

[4] Pre-Proposal 由各國推薦之中立專家學者審查。

[5] Final Proposal 除了由 Pre-Proposal 之審查委員審查外，並委請外部(External Reviewer)專家審查。

2018	February 6	Submission deadline for pre-proposals 60 days to prepare pre-proposal
	February 8	Eligibility check –JCS Eligibility check (CSC)
	February 21	Eligibility check JCS + CSC partners; final decision
	February 23	Allocation of pre-proposals to SEC members (start of the first evaluation phase)
	March 30	Deadline for SEC members to deliver the evaluation reports on the pre-proposals
2019	April 9-13	First JTC 2017 SEC meeting & CSC meeting + NSC meeting + Joint NSC-SAB meeting
	April 18	Invitation of successful coordinators to submit full proposals. Opening of the on-line submission system for full proposals
	April 19/20	Communications to unsuccessful coordinators
	May 30	Submission deadline for full proposals 6 weeks to prepare the full proposals
	May 31	Give access to the submitted full proposals to CSC
	June 6	Eligibility check of full proposals (JCS&CSC) and final decision
	June 13	Allocation of full proposals to SEC members and to external reviewers (start of the second evaluation phase)
	August 1	End of evaluation (SEC + external experts)
	August 2-6	Invitation of coordinators to submit comments for the rebuttal stage. Preparation of the on-line submission system for rebuttal stage.
	August 7-17	Rebuttal stage 10 days for the applicants to response to reviewers' comments
	September 10-14	Second JTC 2017 SEC meeting & CSC meeting + NSC meeting
	September 28	Final funding decision (i.e. approval by CSC members)
	October week 2	Short communication of final funding decision to successful full proposals
	October week 3	Short communication of final funding decision to rejected full proposals
	November week 4	The JCS will communicate the reasons for approval to the coordinators of the successful full proposals
	December, week 1	The JCS will communicate the reasons for rejection to the coordinators of unsuccessful full proposals
2019	April	Start of research projects

2020	February 28	Year 1 report
2021	February 28	Year 2 report
2022	June 30	Year 1 - 3 final report

九、 本次徵求主題

Translational Research on Rare Cancers

The decisions concerning the focus of the present call are strongly motivated by the challenges related to research and treatment in rare cancers, which are intimately tightened to the low incidence of any single clinical-pathological entity currently listed among these cancers. Proposals will have to cover a minimum of one of the specific aims reported below, and within the aim/s of choice, the applicants will have to address at least one of the topics listed as bullet points. Proposals addressing one single aim and one single bullet point within the chosen aim will be allowed.

(一) Aim 1: Design and conduct of translational research studies exploiting/combining resources from current clinical trials, bio-repositories and epidemiology-type resources.

Translational cancer research on aetiology, pathogenesis and prognosis of rare cancers is tightly linked to the integrated use and facilitated access to biospecimens from patients. Translational research goals in rare cancers may thus be achieved throughout studies of cohorts of patients with available biospecimens adequately stored in biorepositories linked to cancer registry data.

- Translational studies based on the analysis of data and/or of clinically annotated specimens from previously conducted/ongoing trials with adequate follow up.
- Conduct of studies for cancer risk assessment in rare cancers leveraging upon access to institutional and/or national cancer registries.

- Identification and characterization of the etiopathogenetic determinants involved in rare cancers aiming at increasing our knowledge of the underlying pathways to be targeted by means of existing or experimental therapies.

(二) Aim 2: Development and exploitation of translational research platforms (e.g., patient derived xenograft models/organoids/tissue collections) to study drug responses/resistance and toxicity, and perform drug screens or repurpose approved anticancer drugs.

- Tissue collection, and genetic and epigenetic characterization of patient-derived rare tumors xenografts (PDXs). PDX could be used to identify determinants of heterogeneity in patient response to therapy, and thus inform patient-oriented therapeutic decisions. PDX could be used to screen for candidate pathways and/or therapeutics.
- Three-dimensional cultures (or 'organoids') obtained from patients' rare tumors which closely replicate key properties of the original cancers. Organoid cultures could be amenable to the detection of genetic and/or epigenetic changes associated with drug sensitivity and may thus lead the way to targeted approaches that could improve clinical outcomes in cancer patients
- Other translational research platforms that give insights into the drug responses/resistance and toxicity of drugs, and help perform drug screening for the treatment of rare diseases (e.g., induced pluripotent cell clones established from patient tumors and normal cells and induced to differentiate in vitro).

(三) Aim 3: Implementation of precision biomarkers for better stratification of the clinical cohorts.

- Validation and implementation of rare cancers associated biomarkers as molecular predictors of therapeutic response, treatment resistance and disease outcome.
- Use of innovative, high throughput technologies designed to facilitate the comprehensive omic assessment of genomes, transcriptomes, proteomes, metabolomes, etc. of patients affected by rare cancers.
- Design and conduct of phase I and/or phase II clinical studies aiming at the validation and implementation of precision biomarkers (including approaches based on liquid biopsies to enable non-invasive assessment of tumour heterogeneity and to monitor tumour dynamics) in patients diagnosed with rare cancers.

十、 鼓勵人才培育及人員交流

Applicants may add an additional part for **capacity building activities** (with an associated separate budget, in compliance with the rules of the respective national/regional funding organizations). These activities have to be coherent with the objectives of the research project, and aimed to strengthening the ability of participating team(s) to perform the work detailed in the project plan as well as to improve, in the long term, the quality and potential of the translational research performed by the team(s).

Translational research has the ambition to remove barriers to multidisciplinary collaboration. It is envisioned that clinicians, researchers and the operational staff from various sectors (academia, industry, regulatory bodies) will effectively work

together to expedite the translation of scientific discoveries to clinical application and to more rapidly fuel research directions with observational or clinical findings. In fact, the complexity of the process requires, at the individual and collective levels, the creation of translational medicine research interfaces/infrastructures. To reach that goal, TRANSCAN-2 supports capacity building activities for promoting the formation and upgrading of multidisciplinary teams in an integrated process:

(一) exchange/mobility of individual researchers/professionals within the consortium in order to bring new expertise to an existing multidisciplinary translational team, and/or

(二) recruitment of individual researchers/professionals by a translational research team in order to cover expertise and "knowhow" unavailable in the existing team. This type of activities, when present, will be supported within the projects which will be selected for funding under TRANSCAN-2 JTC 2017.

Thus, applicants may add an additional part to cover these activities (with an associated separate budget, in compliance with the rules of the respective national/regional funding organisations). These capacity building activities have to be fully coherent with the objectives of the research project, and aimed to strengthening the ability of participating team(s) to perform the work detailed in the project plan as well as to improve, in the long term, the quality and potential of the translational research performed by the team(s). Depending on the project these activities could be (the following examples are indicative only, and neither exhaustive nor prescriptive):

- exchanges/mobility of investigators (especially young investigators) between teams and countries participating in the project,
- short term training of scientists, operational staff, etc.,
- training technical workshop dedicated to relevant aspects of the scientific work planned in the project,
- short training (1 or few weeks) of several partner teams by one expert, etc. Activities related to the dissemination of results such as hosting a symposium, conferences etc. are out of the scope of this capacity building activities component.

十一、 研究計畫書必須符合下列要點

Inclusive criteria:

(一) Rare cancers. This criterion will be applied to each of the proposals submitted for evaluation. Rare cancers will be defined as diseases whose incidence, when individually considered, is lower than 6 newly diagnosed cases per 100.000/year

in Europe. The RARECAREnet cancer list is available at the following link: http://www.rarecarenet.eu/rarecarenet/index.php/cancerlist .

(二) Pediatric cancers. Pediatric cancers will be eligible if listed among rare cancers (http://www.rarecarenet.eu/rarecarenet/index.php/cancerlist).

十二、 TRANSCAN-2 不受理下列類型之研究計畫書

The following types of research projects are **excluded** from the call:

(一) Studies on common cancers, i.e., cancers whose incidence is equal to/greater than 6 newly diagnosed cases per 100.000/year.

(二) Studies on diagnostic and/or prognostic biomarkers only.

(三) Studies on biomarker discovery only.

(四) Studies based on preclinical models only (e.g., transformed cell lines and animal models).

(五) Research limited to clinical trials only.

(六) Phase III and IV clinical trials.

(七) Studies not compliant with the COMMISSION REGULATION (EC) No 800/2008 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:214:0003:0047:en:PDF), with specific reference to the articles 30, 31, 32, and 33. For full reference, please see also the COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS of 20.12.2011 (link). Studies not compliant with the Commission Regulation (EU) No 651/2014 of 17 June 2014 (link).

十三、 審查要點及評分標準

TRANSCAN-2 計畫審查將針對每個審查要點採分數制(0-5 分)辦理，例 3.5 分則介於 Good and Very Good：

0 分: fails to address the criterion or missing information

1 分: criterion poorly addressed/serious weaknesses
2 分: fair/ some weaknesses
3 分: good/ shortcomings are present
4 分: very good/ criterion well addressed
5 分: excellent

(一)審查要點一: Excellence

- Scientific quality of the proposal: soundness of the rationale including transdisciplinary considerations, clarity of the objectives, expected progress beyond the state-of-the-art, international competitiveness.

- Relevance of the project regarding the topic (minimally and non-invasive methods for early detection and/or progression of cancer) and the overall objective (translational cancer research) of the call; availability and quality of preliminary data.

(二)審查要點二: Impact

- Potential impact with reference to the development, dissemination and use of project results: potential impact of the expected results on cancer control, in terms of translation into public health or clinical practices (enhancing innovation capacity and integration of new knowledge) and/or into pharmaceutical/industrial applications; appropriateness of measures for the dissemination and/or exploitation of project results including socio-economic aspects and anticipation of intellectual property issues (patenting, industrial exploitation, marketing, etc.).

- Impact with reference to strengthening the translational capacity building activities:

- This sub-criterion will be assessed at the level of the full proposal only and solely for the scientific proposals recommended for funding.

- The assessment of the capacity building component and associated budget will be performed under this sub-criterion after the scientific assessment of the proposal: hence, a proposal could be recommended for funding without the part related to capacity building activities if this part is evaluated as "poor".

- The assessment under this sub-criterion will be performed independently using the following:

  (a) Content: relevance and coherence of the capacity building activities

with the proposal objectives.

(b) Candidate: background (scientific, medical, etc.), coherence with the CV, scientific production.

(c) Host team: expertise of the host team in the field, research qualification of the responsible person.

(三)審查要點三: Quality and efficiency of the implementation

- Coherence and effectiveness of the work plan: appropriateness and feasibility of the methodology (including the clinical trial if applicable) and associated technologies used, with particular regard to the study design, the study population(s), study endpoints.
- Statistical/bio-statistical aspects and power calculation (including the clinical trial if applicable): study design; sampling calculations; appropriateness and robustness of statistical analyses: adequateness of endpoints.
- Quality of the transnational research consortium: experience of the research partners in the field(s) of the proposal (for young teams: appropriateness of their current work and training of their members); quality of the collaboration between the research teams and added value of the research consortium as a whole.
- Appropriateness of the management structures and procedures, including risk and innovation management.
- Appropriateness of the allocation of tasks and resources to be committed (personnel, equipment, etc.) and of the estimated budget.
- Compliance with ethical rules and regulatory aspects.

單一**審查要點**分數**如果低於 3 分，則將被視為低於標準**；計畫的總分分數如果低於 10 分則將列為未獲推薦。

十四、注意事項

(一) 每件計畫<u>最少</u>必須由 3 個團隊所組成且最多不得超過 7 個團隊[6]，標準

[6] 如果某計畫由 4 個團隊所組成，則仍需維持最低 3 個國家的參與(即可以接受最多不超過 2 個團隊來自於同 1 國，惟必須符合 1 件計畫最少由 3 個國家的團隊所組成的規則)。如某計畫由 5 個團隊所組成，則仍可維持在 3 個 TRANSCAN-2 國家參與(其

3個團隊所組成的計畫必須由最少3個國家的人員所組成(1國組1隊)。超過 3 個團隊的計畫必須符合下列規則:『1 個國家最多不能超過 2 個團隊參與同 1 件計畫』。

(二) 每件計畫上限最多不得超過 7 個團隊，唯一可以破例的前提是團隊中新增來自於 Estonia，Latvia，Slovakia and Turkey 國家的團隊，在此前提下，倘三個國家各自出一個團隊參與同一件計畫，則該件計畫之團隊上限最多可以接受高達 10 個團隊。

(三) 1 件計畫可容許有 1 隊是由非 TRANSCAN-2 計畫參與國家中的團隊參加(但是該計畫仍必須符合基本條件:至少已有 3 個 TRANSCAN-2 計畫參與國的團隊所組成的前提下)。非 TRANSCAN-2 計畫參與國之團隊必須於計畫書中明確表示執行計畫所需經費將會自籌，如該計畫通過第 1 階段 Pre-Proposal 之審查後進入第 2 階段 Final Proposal 之審查，將會被要求提供相關書面證明用以擔保計畫所需之執行經費可以取得。

(四) 每件計畫必須有 1 位計畫主持人(Coordinator)，且計畫主持人必須由 TRANSCAN-2 計畫參與國家中的團隊擔任，並確認符合該國補助機構之申請資格。

(五) 研究計畫團隊之組成必須包含至少 1 個 Basic or Pre-Clinical Research Team 及 1 個 Clinical Team。 註: 原文為 Consortium must involve at least one basic or pre-clinical research team and one clinical team devoted to either bench-to-bed or bed-to-bench studies.

(六) 獲補助之計畫，團隊必須依規定簽署團隊合作協議: It is mandatory for a funded research project consortium to sign a Consortium Agreement (CA), addressing the issues indicated in the document "Guidelines for Applicants". See link for an EU example of a CA. For the composition of the CA, the research consortium is strongly recommended to see legal assistance of a TTO (Technology Transfer Office) at their own institute. Also, the research consortium is strongly recommended to sign this CA before the official project start date. In any case the CA has to be signed no later than six months after the official project start date. The signed consortium agreement must be made available to the concerned TRANSCAN-2 JTC 2017 funding organizations.

(七) Results and foreground IPR resulting from projects funded through the TRANSCAN-2 JTC 2017 will be owned by the organization that employs

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中有 2 個國家各自從自家國出 2 個團隊參加)，亦可以直接由 4 個國家(其中 1 國組 2 個團隊)或 5 個國家參與(1 國組 1 隊)。

the participant who creates the results, respecting to international/national/regional rules on IPR. If several participants have jointly carried out work generating new IPR, they shall agree amongst themselves in the CA as to the allocation of ownership of IPR, taking into account their contributions to the creation of those IPR. European Commission´s guidelines on IPR issues should be respected in TRANSCAN-2 JTC 2017 research projects.

(八) The results of the research project and IPR created should be disseminated and made available for use, whether for commercial purposes or not, in order to maximize public benefit. Dissemination should not conflict protection of IPR. In the CA the parties agree on the procedures for delaying dissemination of results to enable protection of IPR. The delay may not exceed 120 days after the originally planned date of dissemination.

(九) 每件獲 TRANSCAN-2 補助之研究計畫，計畫主持人必須於每年度計畫結束後 2 個月內繳交期中報告並於整個計畫結束後 3 個月內繳交期末報告給 TRANSCAN-2 委員會，所有報告必須用英文撰寫。計畫成員必須配合計畫主持人之協調繳交英文計畫報告資料。

(十) 通過本部核定之 TRANSCAN-2 研究計畫，請依本部相關規定繳交研究成果及結案報告等(建議用英文書寫，因為 TRANSCAN-2 計畫團隊會向計畫成員索取 1 份)。必要時，得請計畫主持人至本部指定場合口頭報告，或配合本部辦理實地考評審查。

(十一) 本徵求公告未盡事宜，應依「科技部補助專題研究計畫作業要點」、「科技部補助專題研究計畫經費處理原則」及其他相關規定辦理。

(十二) 申請本計畫無申覆機制，一切依照歐盟制定之審查機制及各國公認的程序及方式辦理(與所有參與 TRANSCAN-2 會員國適用同標準)。

十五、 承辦人

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