### FORSCHUNGSPORTAL SACHSEN-ANHALT

Forschungsportal-Mailliste EU-Foerderinfo: Querschnitt europäische Forschungsförderung Advanced Manufacturing, HORIZON 2020 IMI -Medikamentenentwicklung, erstellt am 03.07.2020, gültig bis 29.09.2020, Autor: Martina Hagen

#### Inhaltsverzeichnis

	1. /DFG/ NSF and DFG Opportunity for Collaborations in Advanced Manufacturing, no specific deadline	1
	2. /BMBF*/ Projektförderung: EUREKA - Dank Forschung und Innovation in globaler Partnerschaft Krisen meistern, Frist: 15.07.2020, 17:00 Uhr	1
	<ol> <li>/EU COSME*/ Supporting European SMEs to Participate in Public Procurement Outside EU, ID: PPOUT-01-2020, Deadline: 15.09.2020 17:00 Brussels time</li> </ol>	3
	<ol> <li>/EU Horizon2020*/ Restricted Call to maximise impact of IMI2 JU objectives and scientific priorities, ID: IMI2-2020-22-01, Deadline: 29.09.2020 17:00 Brussels time</li> </ol>	4
	<ol> <li>/EU Horizon2020*/ Returning Clinical Trial Data to Study Participants within a GDPR Compliant and Approved Ethical Framework, ID: IMI2-2020-23-01, Deadline: 29.09.2020 17:00 Brussels time, first stage</li> </ol>	5
	<ol> <li>/EU Horizon 2020*/ Modelling the Impact of Monoclonal Antibodies and Vaccines on the Reduction of Antimicrobial Resistance, ID: IMI2-2020-23-02, Deadline: 29.09.2020 17:00 Brussels time, first stage</li> </ol>	6
	7. /EU Horizon2020*/ A Platform for Accelerating Biomarker discovery and Validation to Support Therapeutics Development for Neurodegenerative Diseases, ID IMI2-2020-23-03, Deadline: 29.09.2020 17:00 Brussels time, first stage	7
	8. /EU Horizon2020*/ Optimal Treatment for Patients with Solid Tumours in Europe through Artificial Intelligence, ID: IMI2-2020-23-04, Deadline: 29.09.2020 17:00 Brussels time, first stage	9
	9. /EU Horizon2020*/ Shortening the Path to rare Disease Diagnosis by Using Newborn Genetic Screening and Digital Technologies, ID: IMI2-2020-23-05, Deadline: 29.09.2020 17:00 Brussels time, first stage	10
1	0. /EU Horizon2020*/ Behavioural Model of Factors Affecting Patient Adherence, ID: IMI2-2020-23-06, Deadline: 29.09.2020 17:00 Brussels time, first stage	12



#### Inhalte

### 1. /DFG/ NSF and DFG Opportunity for Collaborations in Advanced Manufacturing, no specific deadline

The pursuit of scientific goals recognizes no geographic boundaries and as such, international collaborations are today more the norm than the exception. To facilitate the support of collaborative work between US groups and their German counterparts, NSF's Civil Mechanical and Manufacturing Innovation Division (CMMI) and DFG's Division of Engineering (ING) have recently agreed on a lead-agency activity in Advanced Manufacturing. US researchers are invited to read the Dear Colleague Letter NSF 20-088.

US-German collaborations are invited to submit joint proposals in the areas described in NSF's Advanced Manufacturing programme and DFG's review board 401 Production Technology. As the projects must be fully integrated US-German research projects, it is expected that the joint proposals contain detailed information about the mode and essentiality of collaboration between the US and the German side. These proposals will be reviewed in a review panel according to the NSF review guidelines in competition with other proposals received in the same NSF programme. A member of DFG's review boards will be involved in the review process. It is important to note that there are no separate funds available for these efforts on each side; proposals must compete with all other proposals in this area. The result of the review process will be shared between the agencies to make final decisions on this basis. Support will be granted for those proposals with both DFG and NSF recommendation for funding.

Proposals are accepted anytime. No specific deadlines apply.

Contact persons:

NSF (Civil Mechanical and Manufacturing Innovation): Khershed Cooper (Tel: +1 703 292-7017, E-Mail: khcooper@nsf.gov) Bruce Kramer (Tel: +1 703 292-5348, E-Mail: bkramer@nsf.gov) Thomas Kuech (Tel: +1 703 292-2218, E-Mail: tkuech@nsf.gov) Andrew Wells (Tel: +1 703 292-7225, E-Mail: awells@nsf.gov)

DFG (Office North America) Bettina Schuffert (Tel: +1 202 729-6350, E-Mail: bettina.schuffert@dfg.de)

DFG (Head Office - Engineering Sciences I) Wieland Biedermann (Tel: +49 228 885-2023, E-Mail: wieland.biedermann@dfg.de) Ferdinand Hollmann (Tel: +49 228 885-2277, E-Mail: ferdinand.hollmann@dfg.de)

Further information:

https://www.dfg.de/foerderung/info\_wissenschaft/info\_wissenschaft\_20\_34/index.html www.nsf.gov/funding/pgm\_summ.jsp?pims\_id=505572&org=CMMI&from=home www.dfg.de/en/dfg\_profile/statutory\_bodies/review\_boards/list/

#### 2. /BMBF\*/ Projektförderung: EUREKA - Dank Forschung und Innovation in globaler Partnerschaft Krisen meistern, Frist: 15.07.2020, 17:00 Uhr

Die aktuelle Coronavirus-Pandemie hat verdeutlicht, wie anfällig unsere Wirtschaft und Gesellschaft aufgrund ihrer weltweiten Verzahnung sind. Es hat sich gezeigt, wie schnell Grundlagen des Wirtschaftens, wie beispielsweise verlässliche Produktions- und Lieferketten, global, national, regional und lokal in Städten und Gemeinden instabil werden können.

Im Rahmen dieser Richtlinie zur Förderung von Projekten werden risikoreiche Forschungs- und Entwicklungsprojekte aus einem oder mehreren der nachfolgenden Aktionsfelder gefördert:

o Lösungen, die die Resilienz und Selbst-Aufrechterhaltung lokaler und regionaler Systeme ermöglichen: Durch hier geförderte innovative Lösungen sollen die Robustheit, Flexibilität und Lernfähigkeit von lokalen und regionalen Systemen, wie z.B. Städten und Kommunen mit ihren Bürgern als Endnutzern, gestärkt werden. So müssen die Versorgung von kritischer Infrastruktur, beispielsweise Elektrizität, sauberes Wasser, Gesundheitsgüter und Verkehr aufrechterhalten werden. Gefördert wird die Entwicklung von innovativen Lösungen, die nicht nur im Pandemiegeschehen, sondern auch in anderen einschneidenden Krisensituationen helfen, Störungen zu widerstehen, sich anzupassen und sich schnellstmöglich zu erholen, ohne langfristige wirtschaftliche Entwicklungsperspektiven zu gefährden. Da viele der hier adressierten Infrastrukturen in europaweite oder globale Netzwerke eingebettet sind, müssen gesuchte Lösungen grenzüberschreitend verwendbar sein und zugrunde liegende Netzwerke möglichst umfassend abbilden. Gesucht wird nach flexiblen und anpassbaren Lösungen, die negative gesundheitliche und wirtschaftliche Auswirkungen lokaler, regionaler, nationaler oder globaler Krisen mildern helfen.

#### o Produktion essentieller Güter - Analysen zum gesellschaftlichen Diskurs:

Oft werden Produkte, die in Deutschland essentiell benötigt werden, beziehungsweise deren Verkauf für Deutschland - nicht nur als Exportnation - von immenser Bedeutung ist, in europäisch und international hochgradig verknüpften Netzwerken hergestellt. Aufgrund komparativer Kostenvorteile verschiedener Weltregionen ergibt sich so eine kostengünstige, gelegentlich aber auch störungsanfällige Bereitstellung dieser Produkte. Dies hat auch die derzeitige Coronavirus-Pandemie verdeutlicht. Gefördert werden hier kooperative Forschungs- und Entwicklungsprojekte mit dem Ziel, durch umfangreiche Analysen von Wertschöpfungsnetzwerken für derartige Produkte einen gesellschaftlichen Diskurs zu stimulieren, in dem die Frage geklärt wird, welche Mehrkosten die Gesellschaft für eine robuste Versorgung mit essentiellen Produkten aufwenden möchte und wie diese getragen werden. Die Analysen sollen verschiedene, insbesondere internationale Krisenszenarien umfassen.

#### o Lösungen zur grenzüberschreitenden Nachverfolgung von Infektionsketten:

Die hohe Verzahnung der deutschen Wirtschaft und Gesellschaft über Ländergrenzen hinweg führt dazu, dass Menschen sich weltweit bewegen müssen und möchten. Damit dies auch zu Zeiten von Pandemien und vergleichbaren Gefährdungen mit gesellschaftlich akzeptablem Risiko möglich ist, sollten Infektionsketten weltweit nachvollziehbar sein ("track and contain"). Derzeit entwickeln zahlreiche europäische Staaten nationale Lösungen1, die nur bedingt miteinander kompatibel sind. Jenseits der EU ist die Kompatibilität eher nicht gegeben. Benötigt wird aber eine Länder- und Kontinente-übergreifende Lösung. Gefördert werden hier kooperative Forschungs- und Entwicklungsprojekte mit dem Ziel, Lösungen für eine solch grenzüberschreitende Nachverfolgung von Infektionsketten zu entwickeln; wobei erste Lösungsansätze sehr schnell (spätestens drei Monate nach Projektstart) verfügbar sein sollten. Die Lösungen sollten - zumindest für europäische Nutzer - den ethischen Werten und dem Datenschutz-Verständnis Europas2 entsprechen. Denkbar sind hier also auch Lösungen, die Informationen aus national verschiedenen Ansätzen kombinieren. Einer breiten internationalen Verwendbarkeit der angestrebten Lösung wird eine hohe Bedeutung beigemessen.

Es sollen innovative neuartige Produkte, Prozesse, Verfahren und Dienstleistungen entwickelt werden. Die Ergebnisse der geförderten Forschungs- und Entwicklungsprojekte sollen falls möglich zwei Jahre nach Projektende verwertbar sein.

Antragsberechtigt sind Unternehmen der gewerblichen Wirtschaft, insbesondere KMU, sowie Hochschulen, außeruniversitäre Forschungseinrichtungen und andere Institutionen, die



Forschungsbeiträge liefern. Nicht antragsberechtigt sind Großunternehmen. Zum Zeitpunkt der Auszahlung einer gewährten Zuwendung wird das Vorhandensein einer Betriebsstätte oder Niederlassung (Unternehmen) bzw. einer sonstigen Einrichtung, die der nichtwirtschaftlichen Tätigkeit des Zuwendungsempfängers dient (Hochschulen, außeruniversitäre Forschungseinrichtungen und andere Institutionen, die Forschungsbeiträge liefern), in Deutschland verlangt.

Das Antragsverfahren ist zweistufig angelegt. Mit der Abwicklung der Fördermaßnahme hat das BMBF derzeit folgenden Projektträger beauftragt: DLR Projektträger Heinrich-Konen-Straße 1 53227 Bonn

Fachliche Ansprechpartnerin ist Frau Dr. Ruth Schietke, EUREKA-Büro (Telefon: +49 2 28/38 21-19 03, E-Mail: Ruth.Schietke@dlr.de) Administrative Ansprechpartnerin ist Frau Anja Kaup (Telefon: +49 2 28/38 21-13 42, E-Mail: anja.kaup@dlr.de)

#### Weitere Informationen:

https://www.eureka.dlr.de/ https://www.bmbf.de/foerderungen/bekanntmachung-3053.html

## 3. /EU COSME\*/ Supporting European SMEs to Participate in Public Procurement Outside EU, ID: PPOUT-01-2020, Deadline: 15.09.2020 17:00 Brussels time

Improving SMEs' access to public procurement is an important objective for the European Commission. Inside the Union, the SMEs' weight in above threshold procurement is still low when compared with their contribution to Gross Domestic Product (only 45% compared to 58%). The participation of SMEs in procurement across borders is even lower.

Public procurement offers major business opportunities to SMEs. In the Union, public procurement represents around EUR 2000 billion per year. When adding the opportunities outside the Union, the potential for growth is even higher. The World Trade Organisation Secretariat estimates the Government Procurement Agreement opportunities amount to US\$ 1.7 trillion annually.

The participation of SMEs in public procurement is a win-win situation. It helps SMEs to grow and scale-up, it improves their reputation, and helps them to obtain more business in the private sector. For public authorities, it increases the number of offers the public buyers get, ultimately increasing the chances to obtain the best value for money.

This action will be implemented through a call for proposals. The projects shall take into consideration several aspects: the identification of the SMEs capacities to operate in an international environment, the sector specificities, and the knowledge and expertise related to certain non-Union partner countries, the knowledge about procurement markets. Therefore, this action will give flexibility to the organisations submitting the proposal to tailor their services to the needs of SMEs while achieving the objectives set in this action. The action could cover several measures such as awareness raising about opportunities existing outside the Union (tenders alerts and guides on what is specific to the respective country on public procurement), training and advisory services to SMEs, business- to-procurers events, partner-finding support, consortia building, etc. In the implementation of this action, the selected consortia should look for synergies with other projects/initiatives developed under COSME or other Union Programmes.

The objective pursued is to improve SMEs' access to public procurement in the non-Union countries with which the Union signed an agreement covering public procurement (for example, the Government



Procurement Agreement of the World Trade Organisation, Stabilisation and Association Agreements, Free Trade Agreements, etc.).

Public procurement contributes to the growth and the global competitiveness of SMEs. The European Union has invested significant resources in negotiating these agreements in order for Union companies to be able to take advantage of the opportunities outside the Union. This action will focus particularly on the public procurement area and falls under the second specific objective of the COSME programme: access to markets.

The projects will have two stages:

1. A preparatory phase, where each project will be requested to develop an internationalisation strategy and its implementation roadmap, based on the targeted Member States and third countries, and

2. The implementation phase, to apply the internationalisation strategy.

In order to achieve the objectives of the action and to have, potentially, economies of scale, the grantees should cover at least three Member States and COSME participating countries. They should target at least two non-Union partner countries with which the Union has signed a trade agreement including a public procurement or are member of the Government Procurement Agreement of the World Trade Organisation.

The current action is designed to ultimately help SMEs to participate in public procurement outside the Union through co-financing actions of intermediate organisations supporting SMEs' internationalisation and participation in public procurement. As a result, these organisations should develop their capacities to help SMEs in this respect, offer more targeted and better support. This measure should complement the efforts done by the EEN in this field and serve as a basis for a better understanding of the SMEs' concrete needs and developing more precise tools.

Qualitative and quantitative indicators for the action:

 Number of business intermediary organisations, clusters and other types of organisations from different COSME participating countries having benefited from the support actions (at least 3 per project).
 Number of SMEs reached by these actions (per project, at least 300 SMEs from 3 Member States).

3. Number of information materials (webinars, interviews with successful companies, etc.) about

non-Union countries (at least 3 per project).

4. Number of "meeting the procurers" events (at least 2 meetings organised per project).

5. Number of partner-matching actions (at least 2 per project).

6. Number of submissions of offers under international procurement procedures during the project.

7. Increase in the percentage of the turnover from international bids won and employment of the SMEs that directly or indirectly benefited from the project.

#### Further information:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details /ppout-01-2020;freeTextSearchKeyword=;typeCodes=1;statusCodes=31094501,31094502,31094503;programCode= ode=COSME;programDivisionCode=null;focusAreaCode=null;crossCuttingPriorityCode=null;callCode=Default;sortQu ult;sortQuery=submissionStatus;orderBy=asc;onlyTenders=false;topicListKey=topicSearchTablePageState te

## 4. /EU Horizon2020\*/ Restricted Call to maximise impact of IMI2 JU objectives and scientific priorities, ID: IMI2-2020-22-01, Deadline: 29.09.2020 17:00 Brussels time

Major challenges in life sciences, in particular within the medicines development process, are the scale of the investment required, the stepwise approach, very long development timelines and the successful

involvement of relevant stakeholders. A platform to facilitate close collaboration is necessary to bring together the critical mass of expertise, knowledge and resources to address these challenges.

The scope of the restricted Call will be to support further research activities in those exceptional cases where it is necessary to enable successful consortia to build on the achievements of their initial action and move onto the next step of the challenge.

Proposals will be evaluated by experts on the basis of the award criteria 'excellence', 'impact' and 'quality and efficiency of the implementation', in line with Article 15 of the Horizon 2020 Rules for Participation (Regulation No 1290/2013). Within these criteria, the experts will focus on the points listed below and the proposals should therefore address them in detail:

o The scientific relevance for successfully addressing the IMI2 JU objectives;

o How the proposed activities relate to an area with a high-unmet need from the public health perspective and having industrial challenges (where relevant). This should also include a landscaping exercise to demonstrate that no similar initiative of the same extent is already ongoing at national, European or global level;

o The need for the proposed activities to (in a timely fashion) seamlessly build on and add value to the already remarkable results achieved in the initial action, as demonstrated and documented by the applicant consortium;

o The scope of proposed activities must fall beyond the scope of the initial action (e.g. initial objectives and its financial and temporal framework). In the event that the new action and the initial one will be running in parallel, measures should be proposed to ensure the achievement of the respective objectives and to ensure that there is no double funding between the initial action and the new action;

o The specific circumstances justifying that only the initial consortium can carry out the follow-up activities successfully. For instance, the initial consortium represents a unique and effective partnership with the expertise, equipment, methodologies, or access to unique resources and IP rights, that are not available from another consortium; if, to cover the expertise for the newly proposed activities, some modifications of the initial partnership is needed, this would have to be justified;

o How the proposed activities build on and benefit from the strong foundations as public-private partnership established in the initial action, e.g. governance, workflows, procedures.

The applicants will also need to justify why the proposed research activities can only be carried out in public private collaboration, including substantial contributions in the project activities of i.e. EFPIA constituents and affiliated entities and, where relevant, by IMI2 JU Associated Partners.

Applicants should define key specific deliverables that address the challenges identified by their proposal and enable the achievement of its objectives. They should also define deliverables that would be sustained beyond the duration of the funded action, and how this would be achieved along with any key results that would be expected to be made openly accessible.

#### Further information:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details /imi2-2020-22-01;freeTextSearchKeyword=;typeCodes=1,0;statusCodes=31094501,31094502,31094503;programCoderamCode=H2020;programDivisionCode=null;focusAreaCode=null;crossCuttingPriorityCode=null;callCode=Default;sc Default;sortQuery=submissionStatus;orderBy=asc;onlyTenders=false;topicListKey=topicSearchTablePageState eState

#### 5. /EU Horizon2020\*/ Returning Clinical Trial Data to Study Participants within a GDPR Compliant and Approved Ethical Framework, ID: IMI2-2020-23-01, Deadline: 29.09.2020 17:00 Brussels time, first stage

A large amount of high-quality health data is collected during clinical studies (interventional and non-interventional), but, beyond the immediate objectives of the study, these valuable data are not used to the extent they merit. Subject to appropriate legal grounds, these data could be used to enrich patients' healthcare records to improve clinical decision-making and reduce duplication in procedures/investigations. In addition, returning clinical trial data to patients could allow them to contribute their data for additional scientific research (e.g. patient-powered research), in particular for rare diseases where treatments and data are scarce or unavailable. Finally, the lack of transparency and sharing of clinical trial data could contribute to the lack of patient willingness to be involved in studies, delays in clinical study set up and conduct, and delays in conducting health research in Europe to the detriment of vulnerable patients and public interest in general.

This project has two main objectives, which are equally important:

o The first one is to align local and pan-European implementations and best practice for handling personal data protection regulations in order to foster the harmonisation of the legal framework applicable to medical research in the Member States;

o The second one is to deliver a pan-European prototype process to return clinical trial data to study participants, building on previous and ongoing EU-level activities on citizen-centric access to health records. This prototype process will be delivered as part of the project alongside a robust business plan to ensure its sustainability.

To support these objectives, the project will:

-Define harmonised rules for complying simultaneously with data protection regulations, regulatory requirements and ethical standards in Europe. These rules are to be endorsed by appropriate regulatory bodies and patients;

-Define which, when and how clinical trial data should be returned to study participants, including for integration in, or interconnection with, patients' individual health records management files or applications and, where they exist, national and/or hospital EHR systems (for clarity, no 'lay summaries' or other expert analyses are within the scope of this project) and EHR standards such as EEHRxF;

-Define data governance models for cases where individual clinical trial data is (or can be) utilised for both healthcare decision making and future research, taking into account previous and ongoing EU-level activities on data governance in these fields;

o Ensure that the whole process, from collection of data to its destruction or anonymisation, including sharing of individual personal data, is aligned with the study participants' expectations and the authorities and ethics committees' standards and procedures, and documented in binding and/or approved standards or guidance documents.

The call has 2 stages.

#### Further information:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details /imi2-2020-23-01;freeTextSearchKeyword=;typeCodes=1,0;statusCodes=31094501,31094502,31094503;programCoderamCode=H2020;programDivisionCode=null;focusAreaCode=null;crossCuttingPriorityCode=null;callCode=Default;sc Default;sortQuery=submissionStatus;orderBy=asc;onlyTenders=false;topicListKey=topicSearchTablePageState eState

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/IMI2\_Cal I23\_CallText.pdf

### 6. /EU Horizon 2020\*/ Modelling the Impact of Monoclonal Antibodies and Vaccines on the Reduction of Antimicrobial Resistance, ID: IMI2-2020-23-02, Deadline: 29.09.2020 17:00

Antibiotics have greatly improved the health and life expectancy of human beings, but antimicrobial resistance (AMR) is rising, and deaths due to infections have been predicted to exceed the ones caused by cancer by 2050. The World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) of the United States have recently listed the priority human pathogens with threatening drug-resistance patterns. New generation antibiotics, vaccines and antibody-based biologics can all contribute to the response to the global challenge of antimicrobial resistant pathogens.

The goal of the project is to develop a framework for setting up antimicrobial resistance (AMR)-focused economic evaluations of vaccines and mAbs. The challenges include a measurement of the present rate of growth of AMR, its main drivers, its health and economic consequences, and which vaccines and mAbs might have the best chance of reducing the rate of AMR growth and the related health and economic consequences. The model will build upon the work done by previous models in depicting the infection dynamics of key pathogens in specific populations that lead to antibiotic consumption and AMR, and will simulate the impact of mAb and vaccination strategies on the chain of events. In a systematic review on AMR mathematical models, Birkegård et al, found that few selected studies fulfilled the TRACE modelling practice guidelines. The recommendations of the authors for future mathematical models on AMR included: "a) model the biological processes mechanistically, b) incorporate uncertainty and variability in the system using stochastic modelling, c) include a sensitivity analysis and model external and internal validation".

The project has the following objectives:

o Evaluate the burden of disease of AMR by estimating inpatients' (acute care hospitals and long-term care facilities) and outpatients' infection rates in at least 8 EU countries for which suitable data is collected and available, as well as in the US28, and the relative attributable risk for morbidity, mortality and costs. o Build a comprehensive AMR model (i.e. model structure, parameters, assumptions) based on an analysis of the strengths and weaknesses of existing models, and a gap analysis.

o Collecting, gathering, and analysing data from existing databases to feed the model.

o Develop and test a cost-effectiveness analysis (CEA) to estimate the cost and benefits of covering defined target groups (e.g. 18+, 60+, surgeries) with mAbs and vaccines.

o Set up a study to test, monitor, evaluate and improve the model.

o Ensure a public and broad access to the model. The model and studies should not target specific bacteria, but should apply as a general tool adaptable to various bacteria

The call has 2 stages.

#### Further information:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details /imi2-2020-23-02;freeTextSearchKeyword=;typeCodes=1,0;statusCodes=31094501,31094502,31094503;programCoderamCode=H2020;programDivisionCode=null;focusAreaCode=null;crossCuttingPriorityCode=null;callCode=Default;sc Default;sortQuery=submissionStatus;orderBy=asc;onlyTenders=false;topicListKey=topicSearchTablePageState eState

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/IMI2\_Cal I23\_CallText.pdf

7. /EU Horizon2020\*/ A Platform for Accelerating Biomarker discovery and Validation to Support Therapeutics Development for Neurodegenerative Diseases, ID IMI2-2020-23-03, Deadline: 29.09.2020 17:00 Brussels time, first stage

Neurodegenerative diseases, and in particular Alzheimer's disease (AD) and Parkinson's disease (PD), represent a huge economic and societal burden. One of the key barriers to the development of treatments for neurodegenerative disease is an insufficient toolbox of biomarkers and associated clinical progression data to easily screen populations, diagnose patients, monitor progression and response to treatment, all of which would improve the efficiency of clinical trials. Investments by both funders and pharmaceutical companies have created significant amounts of data and samples that could be used to accelerate biomarker discovery and development in a major way. However, these valuable resources remain in silos, and cannot easily be shared and accessed by the research community. Key unmet needs limiting the use of samples and data for the discovery, development and validation of neurodegenerative disease biomarkers today include:

o Sample and data access for research use: There is currently insufficient access to high-quality, longitudinal, and well-characterised samples (including clinically well diagnosed and controls) and accompanying clinical data to meet current and future demands.

o Sample quality: A lack of standardisation in collecting and processing samples and linked datasets causes large disparities in sample quality and decreases the utility of banked samples for researchers. o Transparency: There is currently no centralised resource documenting what sample types and accompanying clinical datasets are available across different organisations (public and private), and what access restrictions may be in place.

o Data sharing: Platforms and processes for sharing clinical data to accompany samples and then to enable reutilisation of derived data are lacking or inadequate in terms of interoperability.

There are five objectives in the scope of this topic:

o Create a set of agreed principles to enable sharing and access to data and samples, taking into consideration all the established legal and ethical research standards and principles (e.g. General Data Protection Regulation (GDPR), legal, intellectual property (IP), ethical, regulatory, societal issues) and their practical implementation.

o Establish a network that can house high quality data and samples, which could have federated and centralised elements. This must build on existing ongoing and relevant cohorts (see objective 4). The overall solution has to be interoperable (e.g. with other global data platforms), scalable and suitable for a broad variety of both data types (including digital), and samples, from public and private (e.g. proprietary clinical trials) sources, whether they be part of the consortium or provided from external donors. Activities related to building a biorepository or data management and sharing platform from scratch are out of scope for this topic. Instead, these must build upon existing resources (including ongoing longitudinal cohorts or studies), knowledge and infrastructures to deliver a novel solution able for seamlessly incorporating existing retrospective samples and data with prospective samples and data collections. o Establish fair and transparent governance and processes specifically to enable sharing and access to data and samples.

o Test the above with the defined case studies and apply the learnings to fine-tune processes and use the outcomes to grow the platform. Case studies need to include (but are not limited to) the amyloid-tau-neurodegeneration (ATN) system (in cohorts with early Alzheimer's disease) and the complement pathway (in Parkinson's disease).

o This platform must be a self-sustainable entity by the end of the project.

o The self-sustainable network platform composed of a European biobank operation, and accompanying data platform, will positively fuel and impact basic research and development and drug development campaigns in neurodegenerative diseases, and in particular Alzheimer's disease (AD) and Parkinson's disease (PD);

o The public-private partnership, by providing infrastructure to enable worldwide sample and data sharing will have a substantial impact on the development and regulatory validation of biomarkers/diagnostics, and in turn this would likely have a cascading effect on accelerating therapeutic development.

The call has 2 stages.

Further information:



https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details /imi2-2020-23-03;freeTextSearchKeyword=;typeCodes=1,0;statusCodes=31094501,31094502,31094503;programCoderamCode=H2020;programDivisionCode=null;focusAreaCode=null;crossCuttingPriorityCode=null;callCode=Default;setDefault;sortQuery=submissionStatus;orderBy=asc;onlyTenders=false;topicListKey=topicSearchTablePageState eState

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/IMI2\_Cal I23\_CallText.pdf

## 8. /EU Horizon2020\*/ Optimal Treatment for Patients with Solid Tumours in Europe through Artificial Intelligence, ID: IMI2-2020-23-04, Deadline: 29.09.2020 17:00 Brussels time, first stage

Demands of cancer care in Europe continue to increase significantly, with the number of incident cancer cases in Europe projected to increase by 14.1% by 2030. This leads to a growing demand for innovative cancer treatments among patients, payers, physicians, and society. At the same time, the understanding of the complex biology of cancer is growing, and as a result, pharmaceutical companies are developing a multitude of new therapeutic agents.

This trend for new, effective therapies creates more treatment options for patients. However, it confronts physicians with an increasingly expanding number of potential therapeutic options, which each need to be understood and adopted effectively. To become familiar with the huge volume of available information, physicians need to learn continuously about medical guideline changes and marketed treatments. In conclusion, future decision-making processes will become ever-more complex, with the potential outcome of sub-optimal or even incorrect treatment choices being made. Furthermore, some patients have disease characteristics for which evidence of guideline recommendations is scarce and physicians lack information about real-world treatment outcomes. Hence, the challenges to be addressed are assisted guideline-based decision-making and the discovery of knowledge about treatment outcomes in real-world settings. As the latter challenge requires analysis of large data sets, the application of Artificial Intelligence (AI) will be a key technology.

The scope of this call topic is to establish guideline-based decision support and platform solutions to generate knowledge discovery for breast, lung and prostate cancer with applicability to other indications, in several European (EU member states and H2020 associated countries) 'model' regions. The funded action will focus only on breast, lung and prostate cancer. These indications show a high number of cases per year, a high, unmet medical need, multiple available therapeutic options and a fast-evolving treatment environment. Expansion to other indications is not part of the funded action but a proposed solution should allow for expansion afterwards. The three core objectives of this call topic are as follows:

Objective 1: Establish a guideline-based decision support for prioritised indications Objective 2: Establish a structured and interoperable data platform to unlock real-world-data potential in an oncology network

Objective 3: Leverage the real-world-data gathered by the action to establish an Al-knowledge base and support treatment decisions for prioritized indications.

In their proposals, applicants should describe how the outputs of the project will contribute to the following impacts and include wherever possible baseline, targets and metrics to measure impact. o An explainable AI-based knowledge discovery platform should enable the development of data-driven solutions with the goal to sustainably improve oncologic treatments throughout the EU and beyond;



o The results obtained from these model regions are expected to be of relevance to countries with different socioeconomic backgrounds;

o The platform should allow oncologists to save valuable time due to the automatic data gathering and facilitated guideline-based assessment;

o In addition, physician-patient communication and shared decision making should be supported which might improve proactive therapy involvement to accomplish increases in individual quality of life as well as overall patient satisfaction;

o The platform may also allow research questions from various stakeholders to be answered through data analysis and data pooling as well as data extraction. Besides overall survival, this could include real-world quality of life (QoL) and safety evaluations of new therapies as well as novel combinations under real world conditions. This can potentially contribute to value-based healthcare assessments at EU level; o The solutions provided by a public-private consortium will significantly benefit European society: patients receive optimal personalised treatment; physicians are supported in complex decision-making processes; and payers as well as pharmaceutical companies receive information about real world treatment outcomes as a foundation for value-based healthcare approaches;

o The topic is well aligned with the EU Commission's strategy to develop a European Health Data Space and Europe's Beating Cancer Plan.

The call has 2 stages.

#### Further information:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details /imi2-2020-23-04;freeTextSearchKeyword=;typeCodes=1,0;statusCodes=31094501,31094502,31094503;programCoderamCode=H2020;programDivisionCode=null;focusAreaCode=null;crossCuttingPriorityCode=null;callCode=Default;setDefault;sortQuery=submissionStatus;orderBy=asc;onlyTenders=false;topicListKey=topicSearchTablePageStateestate

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/IMI2\_Cal I23\_CallText.pdf

## 9. /EU Horizon2020\*/ Shortening the Path to rare Disease Diagnosis by Using Newborn Genetic Screening and Digital Technologies, ID: IMI2-2020-23-05, Deadline: 29.09.2020 17:00 Brussels time, first stage

Approximately 5,000-8,000 distinct rare diseases (RD) affect 6-8% of the EU population i.e. between 27 and 36 million people; 263-446 million people are affected globall. Despite scientific advances, in Europe, the fact remains that fewer than 10% of RD patients receive treatment and only 1% are managed using an approved treatment. Delivering effective treatments to RD patients where the prevalence is low has been described as one of the major global health challenges of the 21st century. One of the main challenges for RDs is related to diagnosis because RDs are characterised by a broad diversity of syndromic disorders and symptoms that vary from disease to disease and from patient to patient suffering from the same disease. In isolation, these symptoms can be very common, leading to misdiagnosis. Altogether, this leads to a lengthy and burdensome path to diagnosis that can take, on average, take eight years[1], often involving pointless treatments, creating a heavy human and societal burden that could be avoided by earlier diagnosis.

The overall objective of this call topic is to shorten the path to RD diagnosis by using newborn / paediatric (infants during their first weeks of life) genetic screening; and, via application of advanced digital technologies that enable rare disease diagnosis / identification. The latter might require consolidation of

existing fragmented efforts.

Assessment and development of a comprehensive, strategic overview of existing converging RD resources e.g. databases, registries (such as the EU RD platform), natural history projects, platforms, reference networks, rare disease academic centers of excellence (e.g. European Reference Networks (ERNs)), and initiatives for evaluation / identification of potential collaboration and synergies; Federation of available RD databases into a RD metadata repository amenable to machine learning or other advanced digital tools; Co-creating a sustainable strategy for newborn genetic screening and pilot it. This could start directly after achieving objective 1; Based on the output of objectives 1 & 2:

a) Repurposing of pre-existing diagnosis AI algorithm to identify early onset RD patients in electronic health records (EHRs). This will include at least 3 pilots in better-known rare diseases (with the understanding that solutions and algorithms developed or adapted should be amenable or made amenable to be emulated for larger sets of better-known RDs) where more robust data is available to train and test the AI algorithm(s), and / or;

b) Design and development of new AI algorithm(s) to achieve the above goal.

Based on insights generated by objectives, either repurposing or development of a broad AI RD diagnosis "symptom checker" to help undiagnosed RD patients going from one health care provider (HCP) to another. In addition, exploration of further viable options to implement the symptom checker in actionable solutions for HCPs and patients.

In their proposals, applicants should describe how the outputs of the project will contribute to the following impacts and include, wherever possible, baseline, targets and metrics to measure impact.

The Rare Disease conundrum:

Despite the recent rise in RD research and development, most RDs remain under-studied, and therefore under-treated / cared for. This can be attributed for the most part to:

o Patients are not identified / diagnosed;

o Lack of epidemiological data;

o No natural history of disease data;

o No validated endpoint / patient-reported-outcomes (PROs);

o Patient are rare, experts are even rarer.

This has the pernicious additional effect of blunting interest in diagnosis / screening initiatives, as it would lead to patients being diagnosed with no concrete medical or clinical option. This poses an ethical challenge, which unfortunately feeds the conundrum. This has been identified as a major problem for the rare disease community.

This Call topic anticipates the following benefits:

For patients:

o Decreased time to the right diagnosis;

o Improved patient journey;

o Better healthcare;

o Increased quality of life;

o Decreased irreversible organ damage;

o Access to their own healthcare data.

For healthcare:

o Implementation of digital transformation in healthcare;

o Paradigm change in rare disease diagnosis;

o Improved diagnostic tools;

o Improved understanding of disease;

o Higher accuracy in clinical decisions;

o Better care delivery;



o Integrated care among different specialties. For research:

o Advances in utilisation of digital technologies;

o Increased disease knowledge for future research;

o Improved data availability for future research.

For society:

o Decreased burden for family and carers;

o Increased trust in the healthcare system;

o Better use of data for public health;

o Improved value-based healthcare.

The call has 2 stages.

#### Further information:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details /imi2-2020-23-05;freeTextSearchKeyword=;typeCodes=1,0;statusCodes=31094501,31094502,31094503;programCoderamCode=H2020;programDivisionCode=null;focusAreaCode=null;crossCuttingPriorityCode=null;callCode=Default;sc Default;sortQuery=submissionStatus;orderBy=asc;onlyTenders=false;topicListKey=topicSearchTablePageState eState

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/IMI2\_Cal I23\_CallText.pdf

### 10. /EU Horizon2020\*/ Behavioural Model of Factors Affecting Patient Adherence, ID: IMI2-2020-23-06, Deadline: 29.09.2020 17:00 Brussels time, first stage

Patient non-adherence to prescribed treatment is an issue that affects patient health outcomes and healthcare system costs worldwide. It is estimated that it contributes to 200 000 premature deaths in the EU each year, and the annual costs of avoidable hospitalisations, emergency care and adult outpatient visits are assessed at EUR 125 billion. Addressing the issues of adherence would significantly improve both individual patient outcomes and reduce societal costs.

Many researchers have approached the topic of adherence but insights have necessarily been limited to specific sub-topics due to the breadth of the field. Unless the underlying problem is well-defined and understood, the probability of developing effective solutions with broad and consistent impact is low.

Consequently, there is a need to generate a more comprehensive theoretical and empirical understanding of the underlying causes of these patient behaviours and any interactions. This topic proposes the creation of a generalised model, grounded in behavioural theory, which integrates significant factors affecting non-adherent behaviour. This would provide a robust definition of the problem - a foundation for understanding and predicting patient behaviour - and guidance to develop and implement cost-effective tools and solutions for patients, healthcare professionals (HCPs) and other healthcare stakeholders, which directly target the causes of non-adherence and, ultimately, improve patient outcomes and reduce health system costs.

Creating the necessary understanding for an effective model will require broad engagement and skills, particularly since we are targeting a disease agnostic model. The perspectives of patients, healthcare providers, academic experts, behavioural scientists, digital and data analytics experts, and regulatory bodies will be essential to maximise the benefits and ensure all sectors of society are well served.

The aims of the Call topic are to:



o develop a comprehensive understanding of the factors which affect patient needs and adherence, independently from the therapeutic area (i.e. generic or disease-agnostic), in a real-world context (as opposed to clinical setting);

o identify the most significant factors;

o evaluate existing models and then either create an open access behavioural model or further develop an existing model;

o collect additional real-world data to refine the model;

o provide tools that will enable healthcare stakeholders to cost-effectively develop and implement solutions to address patient needs and improve adherence rates.

A behavioural model will be created or selected and refined. In parallel, adherence modules will be added to existing patient studies to fill identified gaps in the data.

While disease-agnostic, the model should be able to increase the prediction power and accuracy when applying additional, disease-specific inputs.

Once developed or refined, the model will be validated for multiple ages (including paediatric), ethnicities and conditions. It is anticipated that this shall be achieved using the following therapeutic areas, dependent on access to patients provided by members of the consortium:

o Cardiovascular;

- o Oncology;
- o Immunology;

o Neurology;

o Endocrinology and

o Rare Disease.

This list is not exhaustive. Where opportunities arise to validate in other additional therapeutic areas, these should be explored.

The call has 2 stages.

#### Further information:

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details /imi2-2020-23-06;freeTextSearchKeyword=;typeCodes=1,0;statusCodes=31094501,31094502,31094503;programCode ramCode=H2020;programDivisionCode=null;focusAreaCode=null;crossCuttingPriorityCode=null;callCode=Default;so Default;sortQuery=submissionStatus;orderBy=asc;onlyTenders=false;topicListKey=topicSearchTablePageState eState

https://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/IMI2\_Cal I23\_CallText.pdf