



Manifestaciones de interés relativas a la participación en el potencial Proyecto Importante de Interés Común Europeo (IPCEI) de Salud en el marco del Plan de Recuperación, Transformación y Resiliencia

## Introducción

El 27 de abril de 2021, el Gobierno aprobó el Plan de Recuperación, Transformación y Resiliencia<sup>1</sup>, entendido como un proyecto de país que orienta la modernización de la economía española, la recuperación del crecimiento económico y la creación de empleo, la reconstrucción sólida, inclusiva y resiliente tras la crisis de la COVID, dando respuesta a los retos de la próxima década.

El nuevo Fondo de Recuperación *Next Generation EU* permitirá a España movilizar un volumen de inversión sin precedentes. En efecto, el acuerdo del Consejo Europeo prevé financiación por hasta 140.000 millones de euros en transferencias y créditos en los próximos seis años, un 11% del PIB de 2019.

La movilización de un volumen tan importante de recursos abre una oportunidad extraordinaria para nuestro país, comparable a los procesos de transformación económica producidos a raíz de la incorporación a las Comunidades Europeas en los años 80 o la creación del Fondo de Cohesión europeo en mitad de los 90. Permitirá no solo la superación de la crisis y la recuperación del empleo, sino que facilitará la modernización de nuestra economía, para que esa recuperación sea verde, digital, inclusiva y social. Se pondrán en marcha transformaciones y reformas estructurales dirigidas a la transición hacia una economía y sociedad climáticamente neutras, sostenibles, circulares, respetuosas con los límites impuestos por el medio natural y eficientes en el uso de recursos.

## Objeto.

Para garantizar la eficacia del Plan y asegurar la eficiencia en el desarrollo de los distintos proyectos, el Centro para el Desarrollo Tecnológico Industrial E.P.E. (CDTI), publica la presente **petición de manifestaciones de interés con el objeto de identificar a las empresas españolas que podrían participar en un potencial Proyecto Importante de Interés Común Europeo (IPCEI) de Salud y en las futuras convocatorias que lo financien.**

La información que se recopile mediante estas manifestaciones de interés tiene como objetivo ayudar a la definición de las líneas estratégicas de actuación en este ámbito, así como, en su caso, los mecanismos de financiación asociados.

## Presentación de manifestaciones de interés.

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<sup>1</sup> <https://portal.mineco.gob.es/es-es/ministerio/areas-prioritarias/Paginas/PlanRecuperacion.aspx>

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El **plazo de presentación** de las manifestaciones de interés comenzará el día 6 de junio de 2022 y finalizará el día 24 de junio de 2022<sup>2</sup>, a las 12:00 horas del mediodía, hora peninsular. Las manifestaciones de interés recibidas después de esta fecha no serán tenidas en cuenta.

La cumplimentación y presentación de las manifestaciones de interés deberá realizarse obligatoriamente a través de la sede electrónica del Centro para el Desarrollo Tecnológico Industrial E.P.E. (<https://sede.cdti.gob.es/AreaPrivada/Expedientes/accesosistema.aspx>), lo que requerirá el registro previo de los proponentes en el sistema de entidades de CDTI.

La presentación de la documentación requerida se realizará mediante firma electrónica cualificada y avanzada. El certificado electrónico con el que se realice la presentación deberá corresponder al representante legal o apoderado de la empresa solicitante.

Las manifestaciones de interés deberán incluir la documentación que se relaciona a continuación (los formatos de fichero admitidos para toda la documentación son los que corresponden a las siguientes extensiones: «pdf», «rtf», «txt», «doc» y «xls» y en ningún caso superará 3 Mbytes de información):

1. Memoria de la manifestación de interés, según el formato y contenido mínimo reflejados en el modelo del **Anexo II** del presente documento.
2. Dos anexos a la memoria, según el formato y contenido mínimo reflejados en el modelo del **Anexo II** del presente documento.
3. Declaración responsable de la entidad del cumplimiento del Reglamento (UE) 679/2016, de 27 de abril de 2016 (Reglamento General de Protección de Datos) y de no estar sujeta a legislaciones ajenas a la Unión Europea en materia de protección de datos, según el formato del modelo del **Anexo III** del presente documento.
4. Escrituras de constitución de la empresa proponente.

Tanto la memoria como los anexos se deberán presentar en **inglés** (con la única excepción de la declaración responsable, que deberá ceñirse al modelo incluido en la memoria). La memoria tendrá una **limitación de 35 páginas**. Las memorias que superen el límite establecido no serán tenidas en cuenta para su análisis.

Los proponentes podrán remitir una única manifestación de interés, que podrá incluir a otras entidades como colaboradoras. La subcontratación no se considerará colaboración efectiva.

Se garantizará la confidencialidad de la información enviada y el reconocimiento de la propiedad intelectual e industrial.

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<sup>2</sup> Ampliado de manera excepcional el plazo de cierre, desde las 12:00 del 29 de junio a las 12:00 del 1 de julio de 2022, para propiciar una mayor participación de empresas, hasta las 12:00 horas del mediodía, hora peninsular

La participación en la presente consulta no constituye una solicitud de ayuda, no generando derecho alguno al acceso a la potencial financiación que pueda convocar la Administración para la consecución de los objetivos propuestos, ni obligación alguna a la Administración.

## Contexto estratégico del IPCEI de Salud.

El Tratado de Funcionamiento de la UE (TFUE)<sup>3</sup> prevé en su artículo 107.3.b) que podrán considerarse compatibles con el mercado interior las ayudas para la realización de proyectos importantes de interés común europeo (IPCEI por sus siglas en inglés).

La comunicación de la Comisión Europea sobre IPCEI<sup>4</sup> desarrolla el artículo 107.3.b) del TFUE, ofreciendo a los Estados Miembros orientaciones destinadas a impulsar el desarrollo de proyectos en colaboración a gran escala que fomenten los intereses comunes europeos, aporten importantes beneficios a la Unión y que, estando financiados con fondos públicos nacionales que puedan constituir ayudas de Estado, garanticen unas condiciones equitativas en el mercado interior. Estos IPCEI permitirían combinar conocimientos, experiencia, recursos financieros y actores económicos de toda la Unión con el fin de remediar importantes deficiencias del mercado o sistémicas y retos sociales a los que no se podría hacer frente de otra manera.

El IPCEI, bien como proyecto único o bien como conjunto de proyectos integrados que compartan un objetivo común y que estén estructurados bajo un plan coherente, debe cubrir una cadena de valor identificada y demostrar:

- El interés común europeo, mediante el apoyo a los objetivos y estrategias de la Unión y la generación de beneficios tangibles generalizados (más allá de las entidades, sectores y Estados Miembros participantes).
- Su importancia: en términos cuantitativos (tamaño) y/o cualitativos (alcance y riesgo tecnológico o financiero).
- Los fallos de mercado o sistémicos que justifican como única alternativa posible el uso de este instrumento extraordinario de financiación pública, que deberá respetar el mercado interior.
- Un salto cualitativo en términos del valor añadido y carácter innovador, pudiendo abarcar desde actividades de I+D+I hasta primeros despliegues industriales.

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<sup>3</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=ES>

<sup>4</sup> [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC1230\(02\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC1230(02)&from=EN)

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El nivel máximo de ayuda de Estado al potencial IPCEI (financiación pública) se determinaría respecto al déficit de financiación<sup>5</sup> identificado en relación con los costes subvencionables. Si está justificado por el análisis de déficit de financiación, la intensidad de la ayuda podría alcanzar hasta el 100 % de los costes subvencionables, si bien el beneficiario debe participar en la cofinanciación del proyecto.

La ejecución de un IPCEI de Salud, alineado con las estrategias y acuerdos europeos referidos en la introducción, contribuiría a fomentar de manera efectiva que la UE pudiera avanzar hacia el liderazgo europeo en estas materias.

Se prevé que este IPCEI podría comenzar su ejecución en 2023 y finalizar en 2025.

## Selección de las manifestaciones de interés

Las manifestaciones de interés deberán formularse teniendo en cuenta el contexto estratégico descrito anteriormente.

El CDTI podrá solicitar la ampliación o aclaración de la información contenida en la manifestación de interés.

La documentación presentada será analizada por el CDTI en dos fases:

**Fase 1: ELEGIBILIDAD.** Las propuestas que no cumplan los siguientes criterios serán descartadas, sin posibilidad de proceder a la siguiente fase:

1. Presentación en plazo y forma.
2. Las entidades proponentes deberán ser empresas válidamente constituidas.
3. Los proponentes deberán garantizar el cumplimiento del Reglamento (UE) 679/2016, de 27 de abril de 2016 (Reglamento General de Protección de Datos).
4. Las proponentes deberán garantizar que no están sujetas a legislaciones ajenas a la Unión Europea en materia de protección de datos.
5. La memoria de la propuesta deberá adecuarse exactamente al modelo facilitado en el **Anexo II** y cubrir al menos una de las áreas de la cadena de valor y una de las tecnologías identificadas en el **Anexo I** del presente documento.
6. Para que puedan considerarse parte de un potencial IPCEI, las propuestas deben ser importantes cuantitativa y cualitativamente, es decir, deben tener un tamaño y un alcance particularmente grandes y/o suponer un nivel de riesgo tecnológico o financiero muy elevado.

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<sup>5</sup> El **déficit de financiación** (“*funding gap*”) es la diferencia entre los flujos de tesorería positivos y los negativos mientras dure la inversión, descontada de su valor corriente sobre la base de un factor de descuento apropiado que refleje la tasa de rentabilidad necesaria para que el beneficiario lleve a cabo el proyecto sobre todo teniendo en cuenta los riesgos que comporte. Los costes subvencionables son los que figuran en el anexo del documento (2014/C 188/02).

7. Las empresas proponentes deberán acreditar su trayectoria de ejecución de proyectos de I+D+I en España, así como que las actividades de I+D+I vinculadas al IPCEI se ejecutarán en España.

**Fase 2: VALORACIÓN.** Una vez superada la primera fase, las propuestas presentadas se analizarán de conformidad con los criterios que se indican a continuación:

	MEMORIA DE LA MANIFESTACIÓN DE INTERÉS	Peso
1	<b>VALORACIÓN DE LA TECNOLOGÍA, INNOVACIÓN Y PRIMER DESPLIEGUE INDUSTRIAL DEL PROYECTO</b>	50%
	<p>En este apartado se valorarán positivamente:</p> <ol style="list-style-type: none"> <li>1. El grado de ambición, innovación y excelencia en todas las fases: desde las áreas tecnológicas abordadas en la fase de I+D+I del potencial IPCEI hasta el primer despliegue industrial, pasando por la realización de demostradores y pilotos.</li> <li>2. La contribución e integración prevista de las actividades de I+D+I y del primer despliegue industrial en la cadena de valor europea definida para el IPCEI.</li> <li>3. La colaboración y coordinación con potenciales socios españoles y europeos en el marco del IPCEI.</li> <li>4. La adecuación tanto de los de los objetivos vinculados a las estrategias europeas como de los objetivos tecnológicos específicos perseguidos por el IPCEI.</li> </ol>	
2	<b>VALORACIÓN DEL PLAN DE INVERSIÓN DEL PROYECTO</b>	20%
	<p>En este apartado se valorarán positivamente:</p> <ol style="list-style-type: none"> <li>1. La viabilidad y coherencia del plan de inversión completo, desde las fases de I+D+I hasta (i) el primer despliegue industrial; (ii) comercialización/producción en masa.</li> <li>2. La justificación de la necesidad, el efecto incentivador y la proporcionalidad de las ayudas de Estado.</li> <li>3. La descripción adecuada de la potencial distorsión de la competencia originada por las ayudas.</li> <li>4. La justificación del presupuesto estimado en relación con los objetivos del proyecto</li> </ol>	
3	<b>VALORACIÓN DE LA CAPACIDAD DE LA EMPRESA EN RELACIÓN CON EL PROYECTO</b>	20%
	<p>En este apartado se valorarán positivamente:</p> <ol style="list-style-type: none"> <li>1. La coherencia del proyecto con las estrategias de I+D+I y de explotación del proponente.</li> </ol>	

	<ol style="list-style-type: none"> <li>2. Las capacidades, los recursos y la trayectoria de ejecución de proyectos de I+D+I en España.</li> <li>3. La capacidad y experiencia previa del proponente en proyectos de cooperación tecnológica internacional en el marco de la UE.</li> <li>4. La adecuación del presupuesto a las capacidades y al tamaño del proponente.</li> </ol>	
<b>4</b>	<b>VALORACIÓN DEL IMPACTO SOCIOECONÓMICO Y MEDIO AMBIENTAL</b>	<b>10%</b>
	<p>En este apartado se valorarán positivamente:</p> <ol style="list-style-type: none"> <li>1. El impacto del proyecto en la capacidad competitiva del beneficiario y del sector en la UE.</li> <li>2. La descripción adecuada de los fallos de mercado en el ámbito de actuación específico del proyecto.</li> <li>3. Las externalidades positivas generadas ("<i>spillover effects</i>").</li> <li>4. La inversión privada movilizada, creación de empleo para el desarrollo del proyecto y estrategia de desarrollos futuros relacionados con el proyecto.</li> <li>5. Contribución del proyecto a la mejora de la sostenibilidad ambiental.</li> </ol>	
<b>TOTAL</b>		<b>100%</b>

En los casos de propuestas que obtengan igual puntuación y a efectos de resolver el empate, este se dirimirá a favor de la solicitud que tenga mayor puntuación en la valoración del criterio 1. Si se mantuviera el empate, se decidirá a favor de la solicitud que tenga mayor puntuación en la valoración de los criterios 2, 3 y 4 por este orden. Si persistiera el empate, este se arbitrará finalmente a favor de la propuesta si hubiera sido presentada por una PYME.

Una vez superadas las fases descritas, las manifestaciones de interés serán priorizadas, seleccionándose aquéllas mejor posicionadas en la lista prioritaria. El resultado del proceso anterior se comunicará a las empresas seleccionadas, publicándose asimismo en la página web de CDTI.

La selección de las propuestas no genera en ningún caso derecho al acceso a la potencial financiación que pueda convocar la Administración para la consecución de los objetivos propuestos, u obligación alguna a la Administración.

Las empresas cuyas solicitudes sean seleccionadas deberán integrarse en un esquema de colaboración con socios nacionales y de otros EE.MM. e involucrarse en un proceso de notificación de ayudas de Estado ante la Comisión Europea (COM) y coordinado entre todos los EE.MM. participantes. A tales efectos las empresas deberán colaborar con las autoridades nacionales en este proceso, debiendo facilitar la documentación e información precisa para ello.

La COM evaluará la idoneidad de cada uno de los proyectos que integren el IPCEI, pudiendo descartar cualquiera de ellos. Tanto la aprobación final de los proyectos, como la eventual financiación que, en su caso, se otorgue quedarán supeditadas a la decisión final de la COM.



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## Anexo I: Objetivos y áreas tecnológicas del IPCEI de Salud.

At the beginning of March 2022, Austria, Belgium, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Slovenia and Spain took the decision of committing to deepen the work towards the deployment of “Important Projects of Common European Interest” (IPCEI) to further address potential market failures impeding innovation and improve quality of, and access to, healthcare of patients. In this sense, a Manifesto was signed indicating that the projects under this initiative target three main objectives.

- provide an important contribution to the European Health Union.
- contribute to the first industrial deployment of fundamentally innovative production processes, in particular sustainable ones, that would be impossible without the aid granted.
- foster state-of-the-art, quality, and accessible healthcare through the development of new products and services with a high research and innovation content.

Complementarily, projects supported should address proven market failures and bring through wide positive externalities for the whole European Union. They should be the best means to achieve our policy goals compared to alternative financial and regulatory policy response mechanisms.

The Manifesto mentions a time scale that includes two waves. This call of expressions is related to the first of these waves and considers projects related to the following technological areas:

- (i) innovating and greening production technologies and processes for medicines/drug products.
- (ii) innovation in antimicrobial resistance and rare diseases, as well as in emerging health threats where complementary to HERA.
- (iii) developing cell and gene therapies, including production processes and technologies.

This document identifies the five objectives that define the basis and contribution expected of the projects of this initiative to some of the EU strategic policies, which are highlighted in the following paragraphs.

### **Contribution to objectives of the EU**

In accordance with point 14 of the IPCEI guidelines<sup>6</sup>, the Integrated Project will contribute in a concrete, clear and identifiable manner, to several objectives of the EU. It will complement and work in synergy with other European policies and programs.

## **Objective #1: Contribution to the EU Industrial Policy Strategy**

The COVID-19 crisis has strongly affected the EU economy. It exposed the interdependence of global value chains and demonstrated the critical role of a globally integrated and well-functioning Single Market. The New industrial Strategy for Europe, updated in 2021, takes into account the lessons learned from this crisis and a need for sustained investment. In particular, it focuses on: 1) Strengthening the resilience of the Single Market, 2) Supporting Europe's Open Strategic Autonomy through dealing with dependencies, and 3) Supporting the business case for the green and digital transitions.

As part of a toolbox to reduce and prevent strategic dependencies in areas of strategic importance, the Commission committed to continue to support Member States' efforts to pool public resources via Important Projects of Common European Interest (IPCEIs) in areas where the market alone cannot deliver breakthrough innovation.

The Integrated Project will contribute to the New Industrial Strategy for Europe ('Industrial Strategy'), as updated in 2021, and its objective to ensure secured supply chains in strategic areas such as health. The security of supply of medicines has been recognized as one of the central objectives of the Industrial Strategy adopted just before the outbreak of the pandemic. Its update in 2021 has highlighted the issue of dependencies in strategic sectors such as health. The crisis further emphasized the need to strengthen the EU's ability to confront a crisis and act accordingly. The disruptions along the supply chain of the health ecosystem were particularly challenging, resulting from a combination of surging demand as well as supply and workforce shortages, despite the EU's proactive response to ensure (global) transport routes and supply chains remain as open and secure as possible.

The Health IPCEI will imply significant investment to create a major medical advancement in different health sectors and therapeutic areas, and foster European health industries' resilience, which is of strategic importance. Support for the development of innovations in emerging health threats where complementary to HERA will strengthen Europe's preparedness for crises.

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<sup>6</sup> [https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:52021XC1230\(02\)&from=EN](https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:52021XC1230(02)&from=EN)

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It is also worth recalling the need to shape and secure the EU's open strategic autonomy. In this context, the Council conclusions on an EU industrial policy strategy "A vision for 2030" of 27 May 2019 should be recalled: they have emphasized *"the importance of developing pan-European integrated industrial projects involving all interested Member States with the aim of enabling EU industry to face rising international competition and maintaining and further developing high value-added manufacturing activities in Europe"*.

Transformation of processes and practices through innovation is key to stand up to competition in strategic areas. The IPCEI will ultimately contribute to a strong, innovative, and integrated industrial base in the health ecosystem, by pulling together public and private resources and connecting the right players along key value chains at a European level. Furthermore, in line with the objectives of The New industrial Strategy for Europe, the Health IPCEI will support the emergence of highly innovative, digitalised, and sustainable production processes, capable of accelerating the green transition of the European health industries, as well as its resilience and capabilities in key health products, such as APIs or gene and cell therapies.

## Objective #2: Contribution to the European Health Union

### Contribution to the Pharmaceutical Strategy for Europe

The **Pharmaceutical Strategy for Europe**<sup>7</sup> was adopted on 25 November 2020. It aims at supporting industry in promoting research and technologies that reach patients to fulfill their therapeutic needs while addressing market failures. It is based on four pillars, which include : 1) ensuring access to affordable medicines for patients, and addressing unmet medical needs (in the areas of antimicrobial resistance and rare disease, for example); 2) supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines; 3) enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, address medicines shortages; and 4) ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

The initiative will work in synergy with the new Industrial Strategy for Europe and the priorities outlined in the European Green Deal, Europe's Beating Cancer Plan, and in the European Digital Strategy.

In line with the direction set by the European pharmaceutical strategy, the IPCEI will, therefore, be able to set the following objectives:

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<sup>7</sup> European Commission, Pharmaceutical Strategy for Europe, Communication, 25 November 2020 (COM/2020/761 final).

- To prioritize the deployment of major medical advances that will structure tomorrow's health ecosystem and improve the quality, accessibility and safety of care for patients by structuring for instance the biomedicines value chain in Europe, from treatments to production technologies, and allow synergies resulting from complementarity between European startups and their specific assets;
- To reinforce the Union's open strategic autonomy (in complementarity with other instruments like EUFab), thanks, in particular, to the development and greening of innovative production processes throughout the value chain;
- To constitute a tool for responding to unmet medical needs and to address challenges such as antimicrobial resistance and rare diseases, with the aim of strengthening Europe's resilience;
- To foster cooperation and to strengthen collaboration between Member States to support EU pharmaceutical industry competitiveness while avoiding unhealthy competition.

### Contribution to Europe's Beating Cancer Plan

**Europe's Beating Cancer Plan**<sup>8</sup> was adopted on 3 February 2021 as a response to growing challenges and developments in cancer control. The Cancer Plan is structured around four key action areas: 1) cancer prevention, through actions on risk factors (unhealthy diets, physical inactivity, tobacco, alcohol), environmental pollution, HPV vaccination, and health literacy; 2) early detection by improving access, quality and diagnostics and support Member States ensuring that screenings are available; 3) diagnosis and treatment through actions to ensure better integrated and comprehensive cancer care and addressing unequal access to quality care and medicines; and 4) improve quality of life of cancer patients and survivors including rehabilitation, potential tumor recurrence, metastatic disease, and measures to support social integration.

Actions to fight cancer are among the Commission's main priorities. A flagship initiative in the Cancer Plan is the update of the '**Council Recommendation on cancer screening**' (non-legislative, Q3 2022), one of the 'Promoting our European Way of Life' Commission's policy objectives. Moreover, Europe's Beating Cancer Plan together with the Horizon Mission on Cancer is a key pillar of the European Health Union to provide a better understanding of cancer, allow for earlier diagnosis and optimise treatment and improve cancer patients' quality of life during and beyond their cancer treatment.

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<sup>8</sup> European Commission, Europe's Beating Cancer Plan, Communication, 3 February 2021.

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In addition to severely affecting the lives of patients and those close to them, cancer has a significant impact on our healthcare and social protection systems, our workforce and economy, and on the society at large. The overall economic impact of cancer in Europe is estimated to exceed €100 billion annually.

In line with the direction set by Europe's Beating Cancer Plan and the EU Mission on Cancer, one of the Integrated Project's goals is to help research in treatments to cure cancers. Indeed, cell and gene therapies are today a privileged source of innovations in cancer treatment, including rare cancers. In addition, medtech and digital health sectors are paving the way for new solutions in cancer detection, diagnosis, care, treatment, prevention and monitoring for a better quality of life for patients. By supporting innovation in these fields, the IPCEI can therefore position itself as an extension of the Europe's Beating Cancer Plan to enable the emergence of breakthrough medical solutions for the fight against cancer.

### **Objective #3: Contribution to the new European Research Area for research and innovation**

The new European Research Area for research and innovation<sup>9</sup> aims at building common scientific and technological area for the EU. It helps Member states be more effective together through the coordination of their research policies and programs.

As observed by the Commission, the progress towards the R&D objectives has been slowing down and "*further improvement could be achieved in key areas*". Public R&D investment has stalled since 2010, whereas private R&D investment in the EU remains lower than that of other countries such as South Korea, Japan, the United States and in China. In that context, a process to revive ERA was launched in 2018, aiming at inverting this trend and providing an answer for R&I policy demands.

To ensure that a new ERA is fit for any of the challenges ahead, the Commission unveiled a Communication on 30 September 2020. It sets out three new objectives that imply cooperation between Member States: prioritising investments and reforms, improving access to excellence and translating R&I results into the economy:

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<sup>9</sup> [Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – 'A new ERA for Research and Innovation', COM\(2020\) 628 final, 30 September 2020.](#)

- Member states must coordinate their R&I funding. The communication points out that only a small share of revenues are spent by private sector on R&I. EU businesses should be encouraged to increase their R&D investments;
- Member states must strengthen their R&I policies and put forward public private, cross-sectorial interactions that would support private sector innovation. It could be facilitated by coordinating national and EU programmes;
- The Commission will support strengthening European industrial and technological presence in strategic parts of key value chains and fostering open strategic autonomy. The Communication recommends making the best out of industrial alliances and refers directly to Important Projects of Common European Interest (IPCEI), to “bring R&D results towards industrial deployment for the benefit of business and public sector”.

As the shortcomings identified above concern the European healthcare market as a whole, it seems appropriate to launch an IPCEI involving a large number of Member States according to the strengths of their industrial fabric, mature medicines, from chemistry or biomanufacturing, innovative medicines, medical devices, in vitro diagnostics and digital health.

The IPCEI will address this in three ways. First, by increasing the public funds dedicated to research and first industrial deployment in these market segments (e.g. development of novel antimicrobials) through State aid granted under the IPCEI. Second, by encouraging private players to co-invest alongside governments in these market segments. Finally, by helping to bring together European private and public players so that scientific research results can be more regularly translated into patents and medical innovations made available to patients.

In order to ensure the success of projects, the IPCEI offers a unique opportunity to consolidate the value chain of each project through long term partnerships, from basic research to clinical trials and industrial deployment. The structuring of projects around university hospitals specialized in the development and translation of a technology or therapeutic area will enable the creation of true health innovation clusters (e.g. around a critical mass of SMEs, large companies, university and non-university research facilities), to the benefit in particular of the development of small players in the sector.

Structuring projects around specialized clusters will generate a strong traction effect, particularly in the health sector. Structuring health ecosystems through a site-based policy provides the critical mass and proximity between research, care and companies that encourages innovation in health.

The IPCEI will directly contribute to the new ERA as it incentivizes cooperation between the private sector and high quality researchers and innovators across Europe. State aid will allow both private and public research players to position themselves on the riskiest research projects

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- that could not otherwise be supported by the market - while supporting the industrial deployment of these results. It will finally allow to jointly address market failures and common challenges through coordination and pooling of resources. The IPCEI guidelines refer to the new European Research Area.

## **Objective #4: Contribution to the Green Deal**

With the Green Deal, the European Union is pursuing the goal of climate neutrality by 2050. The initiative aims at transforming the EU into a fair and prosperous society, with a modern, resource-efficient, and competitive economy with no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use. In particular, digital technologies are a critical enabler for attaining the sustainability goals of the European Green Deal in many different sectors including the health sector. According to the European Green Deal, the Commission will explore measures to ensure that digital technologies in health sector can accelerate and maximize the impact of policies to deal with climate change and protect the environment. The Commission will also consider measures to improve the energy efficiency and circular economy performance of the sector itself.

One of the main objectives of the Health IPCEI is to help to anticipate and to internalize negative environmental externalities by supporting the risk associated with the initial development and deployment of innovative green solutions with public support. Especially in the highly polluting chemical and pharmaceutical industry, support for innovating and greening production technologies and processes will enable a large-scale green transformation of medicine and drug production, respecting current European environmental standards. It will also help market participants to not solely bear the initial high investment to develop and deploy highly innovative green solutions and to prevent them from passing high costs on to the consumers via premium price.

## **Objective #5: Contribution to the Digital Strategy**

The Digital Strategy<sup>10</sup> addresses a wide range of issues ranging from connectivity, digital value chains and eHealth to the data economy, artificial intelligence, and digital platforms. It is based on three main objectives to ensure a successful digital transition and help the EU taking the lead on the global stage.

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<sup>10</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – ‘Shaping Europe’s digital future’, COM(2020) 67 final, 19 February 2020.

The first objective, a “technology that works for people”, recommends investing in research and innovation, sharing experiences, and cooperating. It highlights the benefits of the “*recent agreements to work together in areas such as supercomputing and micro electronics*”, in reference to IPCEIs. The communication states that similar initiatives on innovative technologies will follow.

Investments in strategic capacities that allow to develop and use digital solutions will be key. The IPCEI wants to bring this ambition to health, where digital technologies open up unprecedented possibilities for prevention and personalised treatment of patients.

The second objective, “a fair and competitive economy”, points out that Europe needs to reduce its reliance on digital solutions created elsewhere. In this regard, the Important Projects of Common European Interest could help Member states lead projects in key, strategic sectors for the digital and green future of Europe.

The third objective “an open, democratic and sustainable society” underlines the importance of data in the health sector. It acknowledges that digitised health records can lead to better treatment for major chronic conditions, including cancer and rare diseases, but also to equal access to high quality health services for all citizens.

The Commission supports pan-European systems and large-scale IT systems that help the implementation of European public services.



## Anexo II: Memoria de la manifestación de interés

El cuerpo principal de la memoria deberá respetar las siguientes condiciones de formato:

- Número máximo de páginas excluyendo la portada, el índice y los dos anexos: 35.
- Tamaño de letra: 11 puntos.
- En la memoria no se tendrán en cuenta los contenidos externos enlazados en esta (hiperenlaces a documentación adicional, etc.).

Se deberán adjuntar obligatoriamente dos anexos al cuerpo principal de la memoria, cuyas plantillas en formato «Excel» se facilitan:

- Análisis del déficit de financiación: plantilla "*Annex I Funding Gap Questionnaire*".
- Cuestionario de la "lista *prod com*": plantilla "*Annex II PRODCOM Template*".

Se proporcionan las guías para rellenarlos en los epígrafes de la memoria.

**Tanto la memoria como los dos anexos se deben presentar en inglés.**

La memoria deberá contener los siguientes epígrafes:

## 1. Project Outline

### 1.1. Company Presentation

Brief description of the company: Company name, type (large, medium, small), contact information (i.e., e-mail address), complete address, main activity, number of employees, annual turnover, etc.

Detailed description of the R&D&I resources and capacities (infrastructure, facilities, staff) located in national premises, specifying which will be allocated to the IPCEI.

### 1.2. Objectives of the company within the IPCEI in all areas involved

Identification of the general objectives of the EU strategies<sup>11</sup> addressed, precisely explaining the project's specific contributions to them.

Concise description of the specific objectives of the project within the areas described in **Annex I** of this document). These objectives must be clear, measurable, realistic, achievable within its duration and consistent with the activities described in sections, 1.4, 1.5 and 3.

### 1.3. Related Research, Development and Innovation (R&D&I) projects previous to the IPCEI

Concise description of the proposer's R&D&I background in this field, including activities necessary for the IPCEI that were carried out before the start of the project, alone or as part of a consortium, both in national and international contexts. This section must be consistent with the proposer's R&D&I strategy in the cloud area.

### 1.4. Technological challenges: R&D&I activities within the IPCEI in all areas involved.

Identification of the relevant Work Packages (WPs). For each WP, brief description of the state of art and of the innovative activities foreseen to solve the current technical challenges within the Technology Areas addressed (i.e., advances over the state of the art). This section must be consistent with sections 1.6 and 1.7.

### 1.5. First Industrial Deployment (FID)<sup>12</sup> activities and investment.

Identification of the relevant WPs. For each WP, brief description of the FID investment (CAPEX) and linked OPEX, clearly explaining when the FID phase starts (after R&D phases) and when the FID phase ends (before mass production/commercialization).. This section must be consistent with sections 1.6 and 1.7.

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<sup>11</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0118&from=es>  
[https://ec.europa.eu/info/sites/info/files/communication-shaping-europes-digital-future-feb2020\\_en\\_4.pdf](https://ec.europa.eu/info/sites/info/files/communication-shaping-europes-digital-future-feb2020_en_4.pdf)  
<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1593073685620&uri=CELEX:52020DC0066>  
<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0575&from=en>  
<https://www.consilium.europa.eu/media/45910/021020-euco-final-conclusions.pdf>  
<https://ec.europa.eu/digital-single-market/en/news/towards-next-generation-cloud-europe>

<sup>12</sup> As defined in the draft 2021 communication from the Commission on IPCEI  
[https://ec.europa.eu/competition/consultations/2021\\_ipcei/draft\\_communication\\_en.pdf](https://ec.europa.eu/competition/consultations/2021_ipcei/draft_communication_en.pdf)

It must be shown that FID activities follow on from R&D&I activities, performed by the proposer or by any other partner in the IPCEI, and contain themselves very important R&D&I components, which constitute integral and necessary elements for the successful implementation of the project.

## **1.6. Work Plan**

Concise description of the work plan, the methodology foreseen and the potential technical and financial risks of the projects. This section must be consistent sections 1.4 and 1.5. Use "*Table 1: Work Plan overview*" below to provide a general overview.

## **1.7. Investments**

### **1.7.1. Tools and equipment**

Concise description of the foreseen investments clustered by technology classification. This section must be consistent with sections 1.4 and 1.5. Use "*Table 2: Investment overview. Tools and equipment*" below to provide a general overview. Provide also a brief description to the table entries (i.e. what the purpose of each investment is).

### **1.7.2. Construction of buildings and/or facilities**

Concise description of the foreseen investments clustered by technology classification and consistent with the activities included in sections 1.4 and 1.5. Use "*Table 3: Investment overview. Buildings and facilities*" below to provide a general overview. Provide also a brief description to the table entries (i.e. what the purpose of the facility is: laboratory, data center, etc.).

## **1.8. Potential partners and subcontractors**

Identification of potential national or European partners in the IPCEI, including a detailed description of the complementarities, synergies and cooperation/coordination mechanisms in the Technology Areas where joint work is foreseen within the potential IPCEI.

Identification and justification of the need for subcontracting national RTOs. Brief description of the tasks to be carried out within the appropriate Technology Areas.

## **1.9. Intellectual Property Rights**

Brief description of the management and exploitation plan for intellectual and/or industrial property rights.

Table 1: Work Plan overview. Use as many rows as necessary (section 1.6)

TA	WP number	Title	P-M		TRL		Date	
			R&D&I	FID	start	end	start	end
		Total PM						

WP: Work Packages (might include one or more TAs)

P-M: Person-Months allocated to the WP.

TA : Technology Area, as described in **Annex I** of this document).

TRL: Starting and ending Technology Readiness Levels<sup>13</sup> foreseen.

Table 2: Investment overview. Tools and equipment (section 1.7.1)

Technology classification	Number of tools	Examples of Tools	Investment Cost [EUR]	Year of investment	TA	WP
		Total EUR				

Table 3: Investment overview. Buildings and facilities (section 1.7.2)

Technology classification	Number of items	Examples of facilities	Investment Cost [EUR]	Year of investment	TA	WP
		Total EUR				

<sup>13</sup> TRLs as defined in [https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016\\_2017/annexes/h2020-wp1617-annex-g-trl\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-g-trl_en.pdf)

## 2. Budget

### 2.1. Eligible Costs of the activities foreseen in the IPCEI

Detailed description of the eligible costs. Eligible costs<sup>14</sup> only cover costs made for the purpose and the time span of the IPCEI. All figures presented in this section must be consistent with the figures included in the "Annex I Funding Gap Questionnaire" Excel file.

Use "Table 4: Summary of eligible costs" below to provide a general overview.

The final result of this section should be a set of three figures:

1. The total amount of eligible costs for the whole IPCEI for R&D&I activities
2. The total amount of eligible costs for the whole IPCEI for FID activities.
3. The total eligible cost of the project proposal (sum of figures 1. and 2. above)

### 2.2. State Aid for the activities foreseen in the IPCEI

Detailed description of the expected State aid, defined as the part of the eligible costs that would be covered by public funding. State aid would only cover costs made for the purpose and the time span of the IPCEI. All figures presented in this section must be consistent with the figures included in the "Annex I Funding Gap Questionnaire" Excel file.

Use "Table 5: Summary of expected State Aid" below to provide a general overview.

The final result of this section should a set of three figures:

1. The expected amount of State aid for the whole IPCEI for R&D&I activities.
2. The expected amount of State aid for the whole IPCEI for FID activities.
3. The total expected amount of State aid for the whole IPCEI (sum of figures 1. and 2. above).

Include the amount of the total cost of the project funded by the company's own resources (i.e. costs that are not eligible but are necessary for the project plus eligible costs of the project that are not expected to be covered by State aid/public funding).

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<sup>14</sup> Eligible costs are identified in the Annex of the Communication from the Commission on IPCEI (2021/C 528/02) [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC1230\(02\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC1230(02)&from=EN)

*Table 4: Summary of eligible costs [EUR]*

	Construction of buildings / facilities	Investment costs	Personnel costs	Subcontract costs	Materials, supplies and others	Total eligible costs
R&D&I						
FID						
TOTAL						

- Costs for each of the categories (R&D&I and FID) should be listed in a disaggregate manner.
- Within the FID costs, the costs of R&D&I based activities carried out in the FID phase should be mentioned to give an idea of the overall importance of the R&D&I components in the FID activities.
- Eligible costs cover costs up to the end of the FID phase, even if the FID phase goes beyond the national granting period for some companies.
- The cut-off dates for the R&D&I and FID phases should be provided explicitly by each company in the “Annex I Funding Gap Questionnaire”.

*Table 5: Summary of expected State Aid*

	Total eligible costs [EUR]	Expected total state aid [EUR]	Expected % of State aid (%)
R&D&I			
FID			
TOTAL			

- Total eligible costs are the “Total eligible costs” figures calculated in Table 4.
- Expected total State aid: part of the eligible costs covered by public funding.
- % calculated as (Expected total State aid/Total eligible costs).

### 3. Expected Impact and Spillover effects

#### 3.1. Impact on competitiveness, investment, employment and the environment

Brief description, including a quantitative estimation wherever it is relevant, of how the innovative nature of the project will contribute to increase:

- The competitiveness of the proposer.
- The creation of qualified employment.
- Potential new investments in this sector in the EU.
- Environmental sustainability.

#### 3.2. Spill-over effects

Clear and concrete identification of the proposer's contributions to the potential IPCEI's spillover effects based on specific commitments. Spillover effects are benefits of the project not limited to the proposer or the sector concerned, but of wider relevance and application to the European economy or society, for example by having systemic effects on multiple levels of the value chain or having alternative uses in other sectors (i.e., positive externalities).

These contributions should:

- Take place during the life of the project.
- Be closely related to the tasks undertaken in the project.

They could include, for example, specific scientific and technical information (not general information) that could lead to third parties to replicate the achieved results.

##### 3.2.1. Spillovers in the R&D&I phase

Identification and brief description of spillovers due to (amongst others):

- Diffusion of non-protected results diffusion: foreseen publications and communications on the results of the IPCEI, open-source software releases, contribution to standards.
- Diffusion of IP protected results: license terms should be as open as possible, for instance non-exclusive "Reasonable And Non-Discriminatory" (RAND) license terms, and may have specific targets (SMEs, start-ups, universities, RTOs).
- Positive impacts on R&D&I ecosystems: transfer of new technologies developed, open infrastructure / testing facilities, training sessions. These spill-over may have specific targets (SMEs, start-ups, universities, RTOs).

### 3.2.2. Spillovers in FID phases

Identification and brief description of spillovers due to (amongst others):

- Positive impacts on industrial ecosystems: deployment of new technologies and open infrastructures made available to SMEs.
- Positive impacts on downstream and upstream industrial or services markets.
- Contributions to standards.

## 4. Market failures

### 4.1. The current market and projections for the future

Brief description of the current EU and worldwide market situation in the specific areas tackled by the project proposal (not the general market): size, growth, competitors, market shares, barriers to entry, new entrants, mergers.

An estimation of the new specific market situation in case the IPCEI finished successfully, based on a description of the product / service that will be commercialized, the competing solutions, the targeted applications, the market segmentation and/or the geographical subdivisions of the market.

### 4.2. The health market failures

Detailed justification of market or systemic failures that prevent the project from being feasible, or being executed to the same extent, in the absence of State aid (public funding) and the way to deal with them (i.e., in which areas and why the cloud market does not currently satisfy the demand in an optimal way). The identified market failures should be specific for the company and the project proposed.

It could include the following (amongst others):

- Imperfect and asymmetric information: Technical and financial risks, difficulties to access market finance or to hire qualified manpower.
- Imperfect competition due to unbalanced market power or high entry barriers for newcomers.
- Coordination failures amongst actors in the sector.
- Negative externalities.

## 5. Incentive effect and necessity of the State aid

### 5.1. Absence of similar projects



Brief explanation of the existence or absence of projects of similar scope and ambition as the potential IPCEI in the EU. The IPCEI would not make sense if its goal were just to replicate technologies already developed by other non-European companies. Would this IPCEI be feasible without State aid?

## **5.2. Start date of the project**

In order to justify the incentive effect of the State aid, the project should not start before the application for State aid (public funding). This IPCEI is foreseen to run from 2023 until 2025.

## **5.3. Counterfactual scenario and incentive effects of the State aid**

Description and substantiation of the counterfactual scenario, i.e. situation where no State aid / public funding is awarded and the IPCEI would not take place:

- Would the proposer undertake an alternative project?
- If so, how would the lack of State aid impact the alternative project, in terms of technology development, industrial deployment and expected business scenarios / capacity?
- If not, how would not undertaking the project impact the proposer's technology development, industrial deployment and expected business scenarios / capacity?

The counterfactual scenario should be described in sufficient detail (e.g., a mere statement such as "the proposer would not undertake the project as planned in its Member State without the aid" is not enough). It should be clearly justified if and why the proposer would not undertake the project at all, or if it would undertake it but in a different manner/extent (an "alternative project"). This alternative project would be a completely different scenario, as compared to the IPCEI, that should be acceptable to the company's stakeholders.

Description of the proposer's intended behavior change as a result of the State aid (i.e., participation in the IPCEI, a new project is triggered, or the size, scope or speed of a project is enhanced) by comparing the expected outcome and level of intended activity with and without State aid.

A description of the level of private profitability and the potential benefits of the project for society in general if the project were undertaken both with and without State aid (i.e., public funding support) should be included.

All information presented in this section must be consistent with the figures included in the "Annex I Funding Gap Questionnaire" Excel file.

## **6. Proportionality of the State aid**

In the absence of an alternative project, the aid amount shall not exceed the minimum necessary for the aided project to be sufficiently profitable, for example by making possible to achieve an Internal Return Rate corresponding to the sector or firm specific benchmark or hurdle rate. In other words, the State aid amount could reach, at most, the funding gap figure or the eligible costs of the project, whichever figure is lower.

### **6.1. Funding gap**

This section shall contain all necessary explanations and a precise justification of the input figures (i.e., WACC used, depreciation time of equipment, etc.) needed to understand how the funding gap was reached, leading to the requested State aid for the future project, and the conclusions of funding gap analysis performed.

The funding gap must be calculated making use of the Excel sheet in “Annex I Funding Gap Questionnaire.xls” (guidance for use in section 7.1).

The funding gap is defined as the difference between discounted positive and negative cash flows over the entire economic lifetime of the investment project, i.e. covering the entire period in which the investments made / produced products and services generate revenues thanks to the project (i.e., the investments are sold on the market). Hence, the funding gap must not be calculated only for the duration of the IPCEI project, which is up to the end of the FID phase, but must also cover the ensuing commercial/mass production phase.

### **6.2. Adequacy of the state aid instrument**

Explain why the State aid instrument would be more adequate to fund such an ambitious project and to correct the market failure as compared to other currently existing public funding instruments.

### **6.3. Limitation of distortion of competition and trade**

Detailed explanation of why the State aid would not lead to the creation of an artificial market structure or generate limitations or distortions in the specific areas of the current global cloud market tackled by the project (not the whole cloud market). The analysis should be based on the following:

- Avoiding the strengthening or creation of market power.
- Limiting distortion of dynamic incentives (i.e., preventing competitors from staying in the market)
- Maintaining an inefficient market structure.
- Avoiding effects on the location of activities undertaken by the proposer.

## 7. Annexes to the proposal

- I. "Annex I Funding Gap Questionnaire.xls"
- II. "Annex II PRODCOM Template.xls"

### 7.1. Guidance for Annex I: the "Funding Gap Questionnaire"

The proposer should provide all eligible costs<sup>15</sup> and revenues associated with the investment as a whole, since the proposal will not only be assessed from the technical side, but also from the perspective of the business investor. Eligible costs only cover costs made for the purpose and the time span of the IPCEI.

The calculation should include all (positive and negative) cash-flows for what the investor regards as the investment project, at the time these cash-flows are to be incurred. It is not enough just to submit the eligible costs. For the purpose of calculating the funding gap, all costs (eligible or not) associated with the investment project and all revenues over the entire lifetime matter, including the commercial / mass production phase will be considered.

**Important reminder: all figures provided in the "Funding Gap Questionnaire" must be consistent with the figures provided in the technical memory.**

The funding gap calculation is to be done according to the following methodology:

- It is sufficient to provide the Excel sheet calculations for the "basic scenario" (i.e., no optimistic and pessimistic scenarios and its respective probabilities are needed, provided that the company is able to justify in the technical memory why this basic scenario is the most likely).
- The funding gap that must be calculated is the funding gap of the investment project (i.e. all investment costs and operating costs) to be made by the company for the purpose of the IPCEI.
- The investments made for the IPCEI in R&D and FID by the company are expected to generate revenues.
- The funding gap is the difference between discounted positive and negative cash flows over the entire economic lifetime of the investment project, i.e. covering the entire period in which the investments made and the produced products and services generate revenues thanks to the project (i.e., the investments are sold on the market). Hence, the funding gap must not be calculated only for the duration of the IPCEI

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<sup>15</sup> Eligible costs are identified in the Annex of the Communication from the Commission on IPCEI (2021/C 528/02)[https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC1230\(02\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC1230(02)&from=EN)

project, which is up to the end of the FID phase (i.e., 2023-2025), but must also cover the ensuing commercial/mass production phase.

- The best estimate projections that the proposer has for this entire period should be included in the Excel sheet. The number of years of commercial/mass production for which data are inserted should be realistic.
- After the data for the FID phase and after the data for the reasonable number of years of the commercial / mass production phase, there should be a column (i.e., the end year of the investment plan considered) containing the terminal value for the costs and for the revenues. In the provided template this end year is 2040 (column W), where cells W99 and cell W100 respectively perform the calculations for the "Residual / terminal value all investments" and the "Discounted value of residual / terminal value all investments". In case the proposer considered an end year different from 2040, cells W99 and W100 should be accommodated to that end year and the content of cell W100 referenced by cell X102 in order to correctly calculate the Funding Gap.
- Sales/revenues (positive cash flows): projected sales figures should be used by each proposer rather than a formula. These should be the figures actually used by the company in its business plan and decision making process and could be best estimate figures.
- Cash flows should be discounted using the weighted average cost of capital (WACC) of the company (cell D118). If so required, the proposer should provide evidence that the discount factor applied is the actual WACC used by the company (e.g. by internal documents showing the applied WACC for investment analysis). The reason to deviate from the WACC usually applied by the company should be explained in detail.
- The depreciation of investments (i.e., equipment, buildings or facilities, cells D115 y D116) should be consistent with the proposer's usual accounting practices.
- **In the absence of a counterfactual alternative project** (justified in section 5.3):
  - There is no need to input data in the counterfactual project tab of the Excel sheet (tab "3\_Counterfactual\_scenario"). Input data would only be required in tabs "1\_IPCEI\_without\_State\_aid" and "2\_IPCEI\_with\_State\_aid".
  - Input figures for tabs "1\_IPCEI\_without\_State\_aid" and "2\_IPCEI\_with\_State\_aid" should be identical except for cell C79 as explained below.
  - For tab "1\_IPCEI\_WITHOUT\_State\_aid", cell C79 ("Grant") **should remain set to 0%**, in order to automatically calculate in cell X102 the right funding gap of the participation in the IPCEI WITHOUT State aid:

- If the value of cell X102 is positive, the State aid would not make sense as the project would be profitable without the support of public funding.
  - If the value of cell X102 is negative, the State aid amount would correspond to the smallest of the following figures:
    - The absolute value of cell X102 (the funding gap of the IPCEI without State aid).
    - The total eligible costs (State aid cannot exceed 100% of the eligible costs identified in any case).
- For tab “2\_IPCEI\_WITH\_State\_aid”, cell C79 (“Grant”) **should be set to a percentage (%)**, consistent with the expected amount of State aid for the whole IPCEI included in section 2 of the technical memory, in order to automatically calculate in cell X102 the right funding gap of the participation in the IPCEI WITH State aid.
- This percentage should always be less than or equal to 100% (State aid cannot exceed 100% of the eligible costs identified in any case).
  - This percentage should yield a value of zero (or positive but close to zero) in cell X102, otherwise:
    - If the value of cell X102 is positive, the State aid would generate profits to the proposer.
    - If the value of cell X102 is negative, the State aid amount would not cover the funding gap.
- The consistency of the funding gap WITHOUT state aid in tab “1\_Project\_WITHOUT\_State\_aid” (cell X102) and the funding gap WITH state aid in tab “1\_Project\_WITH\_State\_aid” (cell X102) will be assessed.
- **In case of a counterfactual alternative project** (justified in section 5.3):
- It is also required to input data in the counterfactual project tab of the Excel sheet (tab “3\_Counterfactual\_scenario”).
  - Cell C79 (“Grant”) in this tab **should remain set to 0%**, in order to automatically calculate in cell X102 the right funding gap of the participation in the counterfactual scenario.
  - The difference between the funding gap of the counterfactual alternative project and the funding gap WITHOUT State aid, respectively in tab

"3\_Counterfactual\_scenario" and tab "1\_Project\_WITHOUT\_State\_aid", will be assessed.

- In this case, the aid amount generally corresponds to the difference between the two funding gaps, but it cannot exceed 100% of the eligible costs identified in any case.

The end result of this process should be one figure for each of the tabs (tabs 1 and 2 in case there is no counterfactual alternative projects or tabs 1, 2 and 3 if there is a counterfactual alternative project): the **amount of the funding gap**, labelled as such in the Excel sheet (cell X102).

## 7.2. Guidance for Annex II: "PRODCOM Template"

Data to be filled in the sheet "1\_DATA\_INPUT" (further information contained in sheet "3\_EXPLANATIONS"):

- 1 The list of PRODCOM codes (contained in sheet "2\_PRODCOM\_LIST") in which the proposer intends to bring out products following the support measure within 10 years from the start of the project,
- 2 The proposer's past 5 years of production values (turnover) in each of these PRODCOM codes, as would be reported for statistical purposes in the PRODCOM survey.
- 3 For each PRODCOM code provided in response to point 1, list the proposer's 5 main competitors.

### List of acronyms used

CAPEX, OPEX	Capital Expenditures, Operational Expenditures
FID	First Industrial Deployment
IPCEI	Important Project of Common European Interest
IP, IPR	Intellectual Property, Intellectual Property Rights
IRR	Internal Return Rate
R&D&I	Research, Development and Innovation
RAND	Reasonable And Non-Discriminatory
RTO	Research and Technology Organization
TF	Technology Field
TRL	Technology Readiness Level
WP	Work Package

### Anexo III: Declaración responsable

#### MODELO DE DECLARACIÓN RESPONSABLE PARA LA ACREDITACIÓN DEL CUMPLIMIENTO DEL REGLAMENTO (UE) 679/2016, DE 27 DE ABRIL DE 2016 (REGLAMENTO GENERAL DE PROTECCIÓN DE DATOS)

D/Dña....., con N.I.F. nº....., en nombre y representación de .....(nombre de la empresa)....., en su calidad de .....(cargo en la empresa)..... con arreglo al nombramiento/apoderamiento realizado ante el notario de (ciudad) don ....(nombre notario)....., con fecha ....(fecha poder)..... y número (.....) de su protocolo, vigente al día de hoy, en relación con la presente petición de manifestaciones de interés relativas a la participación en el potencial Proyecto Importante de Interés Común Europeo (IPCEI) de Infraestructuras y Servicios en la Nube en el marco del Plan de Recuperación, Transformación y Resiliencia

DECLARO bajo mi responsabilidad que la entidad a la que represento cumple en todos sus extremos el Reglamento (UE) 679/2016, de 27 de abril de 2016 (Reglamento General de Protección de Datos) y no está sujeta a legislaciones ajenas a la Unión Europea en materia de protección de datos.

En....., a.....de..... de 2021

Fdo.- D/Dña.....