

IMI2 Key performance indicators (KPIs)

Reporting on measuring and outcomes on the ten following Key Performance Indicators will be provided yearly as part of the IMI2 JU Annual Activity Reports for year 2018 and beyond.

| KPI | Definition | Comment | Relates to | Baseline | Target |
|-----|--|---|--|----------|--------|
| 1 | Number of relevant priority areas in the WHO "Priority Medicines for Europe and the World 2013 Update" reflected in the IMI2 Strategic Research Agenda (SRA) and addressed by IMI2 projects. | Based on the SRA and including the WHO priority medicines therapeutic areas: - Expressed as a number of areas reflected in the IMI2 portfolio. - Complemented by the number and budget of grant agreements that delivered them. | IMI2 Regulation objective b1: b1: "increase the success rate in clinical trials of priority medicines identified by the WHO" | 0 | 12 |
| 2 | The number of project developed assets which complete a significant milestone during the course of an IMI2 project. | Assets are defined as new drug or diagnostic candidates, targets, biomarkers or other tools that can be shown to have reached a significant milestone or pass a significant stage gate. | IMI2 Regulation objective b1, b2, b4, b5 and b6: b1: "increase the success rate in clinical trials of priority medicines identified by the WHO" b2: "reduce the time to reach clinical proof of concept in medicine development..." b4: "develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators" b5: "reduce the failure rate of vaccine candidates in phase III of clinical trials through new biomarkers for initial efficacy and safety checks" b6: "improve the current drug development process by providing the support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products" | 0 | 50 |

| KPI | Definition | Comment | Relates to | Baseline | Target |
|-----|---|--|---|----------|-------------------------------|
| 3 | <p>New or improved guidelines, methodologies, tools, technologies or solutions accepted by regulatory authorities for use in the context of R&D, specifically for:</p> <ul style="list-style-type: none"> - new tools for preclinical drug development, - biomarkers and tools developed to predict clinical outcomes, - improved protocols to design and process of clinical trials, - new biomarkers developed for the efficacy and safety of vaccine candidates. | <ul style="list-style-type: none"> - Measured by the number of the formal qualification procedures completed (letters of support, qualification opinions received). - Complemented by number of qualification procedures launched. - Expressed as net figure. - Complemented by the number and budget of grant agreements that delivered them. | <p>IMI2 Regulation objective b1, b2, b4, b5 and b6:</p> <p>b1: "increase the success rate in clinical trials of priority medicines identified by the WHO"</p> <p>b2: "reduce the time to reach clinical proof of concept in medicine development..."</p> <p>b4: "develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators"</p> <p>b5: "reduce the failure rate of vaccine candidates in phase III of clinical trials through new biomarkers for initial efficacy and safety checks"</p> <p>b6: "improve the current drug development process by providing the support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products"</p> | 0 | 10 (for completed procedures) |

| KPI | Definition | Comment | Relates to | Baseline | Target |
|-----|--|---|--|----------|-----------------|
| 4 | New taxonomies of diseases and new stratifications (such as the definition of patient subpopulations, development, validation and use of new diagnostics) developed. | <ul style="list-style-type: none"> - Expressed as net figure. - As published and/or implemented by industrial partners and evidenced in annual reporting. - Complemented by the number and budget of grant agreements that delivered them. | <p>IMI2 Regulation objective b3 and b4:</p> <p>b3: "develop new therapies for diseases for which there is a high unmet need..."</p> <p>b4: "develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators"</p> | 0 | 30 |
| 5 | Contribution (in-kind or in-cash) from non-pharma actors (e.g. non-pharma industries, foundations, charities, professional organisations). | Expressed as total amount in EUR. | <p>IMI2 Regulation objective a:</p> <p>a: "to support... the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership...";</p> <p>and IMI2 Regulation recital 8:</p> <p>"The initiative should consequently seek to involve a broader range of partners, including mid-caps, from different sectors, such as biomedical imaging, medical information technology, diagnostic and animal health industries."</p> | 0 | EUR 300 Million |

| KPI | Definition | Comment | Relates to | Baseline | Target |
|-----|--|--|--|----------|--------|
| 6 | Share of IMI projects whose resources/outputs are made accessible beyond the consortia partners (with or without fee), such as major databases, bio-banks, in silico tools, training materials, clinical trial networks, guidance etc. | <ul style="list-style-type: none"> - Complemented by the number and budget of grant agreements that delivered them. - Accessibility to be evidenced by online availability (with or without fee), and documented by project reports. | <p>IMI2 Regulation objective a, b2 and b6:</p> <p>a: "to support... the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership..."</p> <p>b2: "reduce the time to reach clinical proof of concept in medicine development"</p> <p>b6: "improve the current drug development process by providing the support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products"</p> | 0 | 50% |
| 7 | Co-authorships and cross-sector publications between European researchers on IMI2 projects (sectors include academia, small and mid-sized companies, pharma, regulators, patient organisations, etc.). | <ul style="list-style-type: none"> - Expressed as net figure - Complemented by the number and budget of grant agreements that delivered them. | <p>IMI2 Regulation objective a:</p> <p>a: "to support... the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership..."</p> | 0 | 1500 |

| KPI | Definition | Comment | Relates to | Baseline | Target |
|-----|---|--|--|---|--------|
| 8 | New tools and processes generated by IMI2 projects that have been implemented by the industry participants of IMI projects. | <ul style="list-style-type: none"> - New tools and processes: e.g. animal models, standards, biomarkers, SOPs, use of screening platforms and clinical trial networks. - Expressed as net figure. - Complemented by the number and budget of grant agreements that delivered them. - Assessment based on yearly reporting by industrial partners until the project close-out meetings. | <p>IMI2 Regulation objective a, b2 and b6:</p> <p>a: "to support... the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership..."</p> <p>b2: "reduce the time to reach clinical proof of concept in medicine development"</p> <p>b6: "improve the current drug development process by providing the support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products"</p> | 0 | 50 |
| 9 | Share of projects involving patient organisations and healthcare professionals' associations (as consortium partners, members of advisory boards, members of stakeholder groups etc). | <ul style="list-style-type: none"> - Complemented by the number and budget of grant agreements that delivered them. | <p>IMI2 Regulation objective a, and b1:</p> <p>a: "to support... the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership..."</p> <p>b1: "increase the success rate in clinical trials of priority medicines identified by the WHO"</p> | Share of IMI 1 projects involving patient organisations: (participants /advisory boards etc. 40%) | 80% |
| 10 | Support to SMEs: share of SMEs participating as formal IMI project beneficiaries. | <ul style="list-style-type: none"> - To be complemented by the number of SMEs benefitting from IMI project support in other ways. | <p>H2020 priority; IMI2 Regulation recital 9</p> <p>"(...) should seek to foster the capacity of smaller actors such as research organisations, universities and SMEs for participating in open innovation models and to promote the involvement of SMEs in its activities, in line with its objectives"</p> | Share of SMEs participating as formal IMI1 project beneficiaries: 15.96% | 20% |