



Report on budgetary and financial management Financial year 2016

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1 Legal and financial framework

Legal framework

IMI2 JU is a Public Private Partnership (PPP) between the EU (represented by the EC) and the European pharmaceutical industry (represented by EFPIA).

IMI2 JU was established, within the meaning of Article 187 of the Treaty on the Functioning of the European Union, by Council Regulation (EU) 557/2014 of 06/05/2014¹ for the implementation of the Joint Technology Initiative on Innovative Medicines.

PPPs are an instrument foreseen by H2020, established by Regulation (EU) No 1291/2013 of the European Parliament and of the Council² to achieve a greater impact with respect to research and innovation by combining EU public funds and private sector funds in key areas where research and innovation can contribute to the Union's wider competitiveness goals, leverage private investment and help tackle societal challenges.

IMI2 JU is established for a period until 31 December 2024. However, in order to take into account the duration of Horizon 2020, Calls for proposals by IMI2 JU shall be launched at the latest by 31 December 2020. In duly justified cases, Calls for proposals may be launched until 31 December 2021.

IMI2 JU replaced and succeeded the IMI JU, established by Regulation (EC) No 73/2008. However, according to Article 19.2 of Regulation 557/2014, actions initiated under Regulation (EC) No 73/2008 and financial obligations related to those actions shall continue to be governed by that Regulation until their completion. Regulation (EU) No 1290/2013³ shall apply to the actions funded by IMI2 JU. In accordance with that Regulation, IMI2 JU shall be considered as a funding body and shall provide financial support to indirect actions as set out in Article 1 of the Statutes.

Financial framework

IMI2 JU has a budget of EUR 3.3 billion for the period 2014-2024⁴. Of this:

- EUR 1.638 billion comes from the Horizon 2020;
- EUR 1.425 billion to be committed to the programme by EFPIA companies;
- up to EUR 213 million can be committed by other life science industries or organisations that decide to contribute to IMI2 as members or Associated Partners in individual projects.

EFPIA companies and other Associated Partners do not receive any EU funding, but contribute to the projects 'in kind', for example by donating their researchers' time or providing access to research facilities or resources.

In accordance with Article 209 of Regulation (EU, Euratom) No 966/2012⁵ on the financial rules applicable to the general budget of the Union and Commission Delegated Regulation (EU) No 110/2014⁶, IMI2 JU has adopted specific financial rules⁷.

¹ OJUE 07/06/2014 L 169/54.

² Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104).

³ Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020)' and repealing Regulation (EC) No 1906/2006 (OJ L 347, 20.12.2013, p. 81).

⁴ During its first phase (2008-2013 established by Regulation 73/2008), IMI JU had a budget of EUR 2 billion, half of which came from the EU's Seventh Framework Programme for research (FP7), and half of which came from in kind contributions by EFPIA companies.

⁵ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

⁶ Commission Delegated Regulation (EU) No 110/2014 of 30 September 2013 on the model financial regulation for public-private partnership bodies referred to in Article 209 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (OJ L 38, 7.2.2014, p. 2).

2 IMI partners and activities

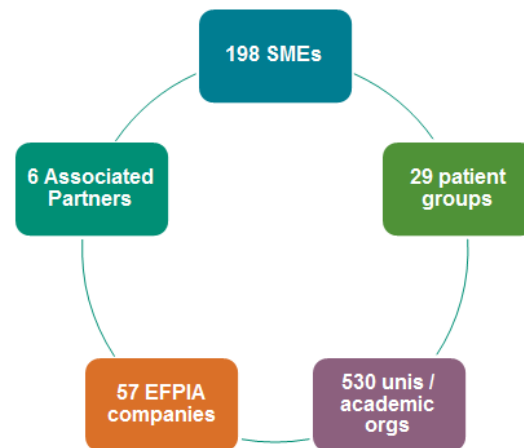
The Innovative Medicines Initiative (IMI) was founded on the principle of open innovation, which means creating a dynamic, networked, multi-stakeholder, collaborative innovation ecosystem. IMI puts open innovation into practice by building ambitious projects that bring together academics, large pharmaceutical companies, small and medium-sized enterprises (SMEs), patient groups, and medicines regulators to join forces and share resources, ideas and expertise to tackle some of the biggest challenges in medical research and drug development. Our open innovation approach allows us to achieve results and make a difference faster and at an unprecedented scale.

Today, the IMI community brings together 11 500 scientists and experts from across Europe and beyond working in 84 projects.

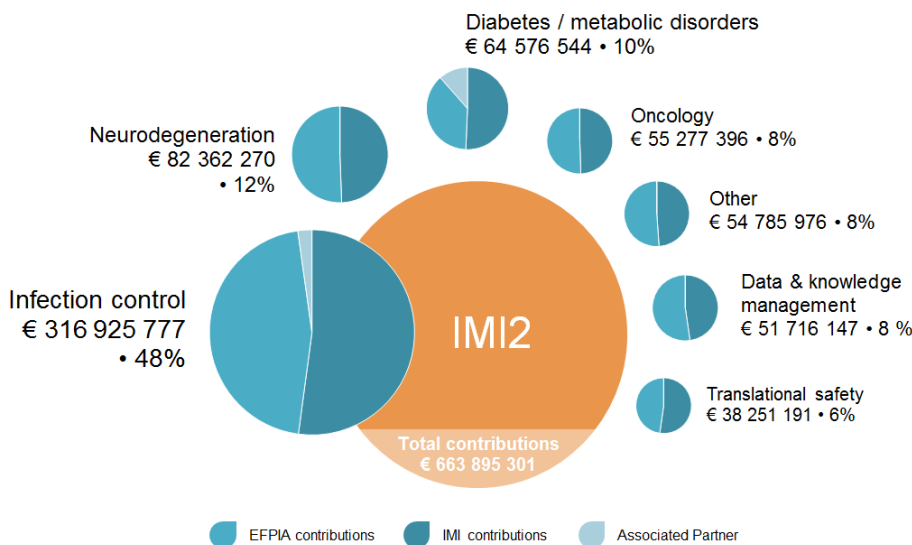
What's more, the IMI community is growing, as 50% of the participants in IMI2 projects were not involved in IMI1.

The graph to the right presents a snapshot of the IMI community today.

IMI projects also cover a wide range of disease and research areas. The graph below shows the breakdown by scientific area of IMI2 projects, including the contributions from the EU, EFPIA companies, and Associated Partners.



Distribution of funding per scientific area - IMI2



Large collaborative projects with diverse stakeholders tend to take people outside their comfort zone; ways of working are open to challenge, old habits (such as not sharing results with 'the competition') have to be unlearned, and prejudices have to be set aside. However, our experience at IMI shows by acting as a neutral broker, IMI helps project partners to overcome these challenges, and our projects are now delivering results that could not have been achieved without the public-private partnership model.

⁷ By way of derogation from Article 60.7 and Article 209 of Regulation (EU, Euratom) No 966/2012, the discharge for the implementation of the budget of the IMI2 Joint Undertaking shall be given by the European Parliament, upon recommendation of the Council in accordance with the procedure provided for in the financial rules of the IMI2 Joint Undertaking.

3 Factsheet - IMI at a glance

Name	Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU)										
Objectives	<p>According to Article 2 of the Council Regulation establishing IMI2, the IMI2 Joint Undertaking shall have the following objectives:</p> <p>a) to support, in accordance with Article 25 of Regulation (EU) No 1291/2013, the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union’s competitiveness and industrial leadership or to address specific societal challenges in particular as described in parts II and III of Annex I to Decision 2013/743/EU, and in particular the challenge to improve European citizens’ health and well-being;</p> <p>b) to contribute to the objectives of the Joint Technology Initiative on Innovative Medicines, in particular to:</p> <ol style="list-style-type: none"> i. increase the success rate in clinical trials of priority medicines identified by the World Health Organisation; ii. where possible, reduce the time to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases; iii. develop new therapies for diseases for which there is a high unmet need, such as Alzheimer’s disease and limited market incentives, such as antimicrobial resistance; iv. develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators; v. reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks; vi. improve the current drug development process by providing support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products. 										
Founding legal act	Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking										
Executive Director	Pierre Meulien										
Governing Board	<p>Representatives of the European Federation of Pharmaceutical Industries and Associations (EFPIA)</p> <table border="0"> <tr> <td data-bbox="435 1599 715 1697">Marc de Garidel Chair, IMI Governing Board</td> <td data-bbox="756 1599 1410 1659">Chairman of Ipsen Group, member of the EFPIA Board and Vice-President of EFPIA</td> </tr> <tr> <td data-bbox="435 1709 687 1738">Richard Bergström</td> <td data-bbox="756 1709 1070 1738">Director General of EFPIA</td> </tr> <tr> <td data-bbox="435 1756 699 1785">Salah-Dine Chibout</td> <td data-bbox="756 1756 1406 1845">Global Head Discovery and Investigational Safety at Novartis, Chairman of the EFPIA Innovative Medicines Strategy Priority Working Group</td> </tr> <tr> <td data-bbox="435 1850 608 1879">Carlo Incerti</td> <td data-bbox="756 1850 1362 1910">Head of Global Medical Affairs at Sanofi Genzyme, member of the EFPIA Board</td> </tr> <tr> <td data-bbox="435 1915 616 1944">Paul Stoffels</td> <td data-bbox="756 1915 1337 2002">Chief Scientific Officer at Johnson & Johnson, Worldwide Chairman of Janssen Pharmaceutical Companies of Johnson & Johnson</td> </tr> </table>	Marc de Garidel Chair, IMI Governing Board	Chairman of Ipsen Group, member of the EFPIA Board and Vice-President of EFPIA	Richard Bergström	Director General of EFPIA	Salah-Dine Chibout	Global Head Discovery and Investigational Safety at Novartis, Chairman of the EFPIA Innovative Medicines Strategy Priority Working Group	Carlo Incerti	Head of Global Medical Affairs at Sanofi Genzyme, member of the EFPIA Board	Paul Stoffels	Chief Scientific Officer at Johnson & Johnson, Worldwide Chairman of Janssen Pharmaceutical Companies of Johnson & Johnson
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Paul Stoffels	Chief Scientific Officer at Johnson & Johnson, Worldwide Chairman of Janssen Pharmaceutical Companies of Johnson & Johnson										

	<p><u>Representatives of the European Commission (EC)</u></p> <p>Ruxandra Draghia-Akli Deputy Chair, IMI Governing Board</p> <p>Irene Norstedt</p> <p>Carlo Pettinelli</p> <p>Andrzej Jan Rys</p> <p>Arnd Hoeveler</p>	<p>Deputy Director-General responsible for Research Programmes within the Directorate-General for Research and Innovation, European Commission</p> <p>Head of Unit responsible for Innovative and Personalised Medicine within the Directorate-General for Research and Innovation, European Commission</p> <p>Director responsible for Consumer, Environmental and Health Technologies within the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, European Commission</p> <p>Director responsible for Health systems, medical products and innovation within the Directorate-General for Health and Food Safety, European Commission</p> <p>Head of Unit responsible for Innovative tools, technologies and concepts in health research within the Directorate-General for Research and Innovation, European Commission</p>
Other bodies	<p>States Representatives Group (SRG): 28 European Union (EU) Member States and 15 Associated Countries to the Horizon 2020 Framework Programme</p> <p>Scientific Committee: 11 members including ad hoc members</p> <p>Stakeholder Forum: 554 registrations in 2016</p> <p>Strategic Governing Groups: 7</p>	
Staff	<p>Total posts: 52 (38 Temporary Agents, 14 Contract Agents)</p> <p>Posts filled: 41 (34 Temporary Agents, 7 Contract Agents)</p>	
2016 budget	<p>Commitment appropriations: EUR 307 052 760</p> <p>Payment appropriations: EUR 263 423 490</p>	
2016 budget implementation	<p>Commitment appropriations: EUR 288 872 480 (94.08 %)</p> <p>Payment appropriations: EUR 183 338 540 (69.60 %)</p>	
Grants	<p>14 grants signed in 2016 for a total value of EUR 135 153 198</p>	
Strategic Research Agenda	<p>The focus of the IMI2 JU Strategic Research Agenda (SRA) is on delivering 'the right prevention and treatment for the right patient at the right time'. No amendment in 2016.</p>	
Call implementation in 2016	<p>Calls launched: 2</p> <p>Short proposals submitted: 60</p> <p>Eligible proposals submitted: 64⁸</p> <p>Full proposals submitted: 21</p> <p>Proposals funded: 19</p> <p>Global project portfolio as of end 2016 (signed grant agreements only): 84 projects (59 under IMI1 and 25 under IMI2)</p>	
Participation, including SMEs	<p>Beneficiaries receiving funds in IMI1 and IMI2 projects represent a range of different types of organisations, including universities, research organisations, small and medium-sized enterprises (SMEs) and patient organisations.</p> <p>SMEs account for 15 % of the total beneficiaries and receive 12.6 % of the IMI budget.</p>	

Note: This factsheet reflects the situation as of 31 December 2016.

⁸ The figure for eligible proposals includes 4 full proposals submitted in response to IMI2 – Call 8, which is a one-stage Call.

4 Budgetary principles

As set out in the IMI2 JU Financial Rules, the budget of IM2 JU was established and implemented in accordance with the principles of unity, budget accuracy, annuality, equilibrium, unit of account, universality, specification, sound financial management and transparency.

5 Overview of the budget

5.1 Initial budget, amending budgets and final budget

The total IMI budget for 2016 was EUR 307 052 760 in commitment appropriations (CA) and EUR 263 423 489 in payment appropriations (PA). The budget execution of the commitment appropriations reached a level of 94.08 %, and payment appropriations reached a level of 69.60 %.

The budget of IMI JU is divided in three Titles:

- Title 1 covers staff expenditure such as salaries, training, costs associated with recruitment procedures and staff well-being.
- Title 2 covers the costs associated with functioning of IMI JU such as renting of premises, IT needs, expenses related to external communication, expert fees and costs of ex-post audits.

Title 1 and Title 2 together form the running costs.

- Title 3 covers operational activities of IMI JU.

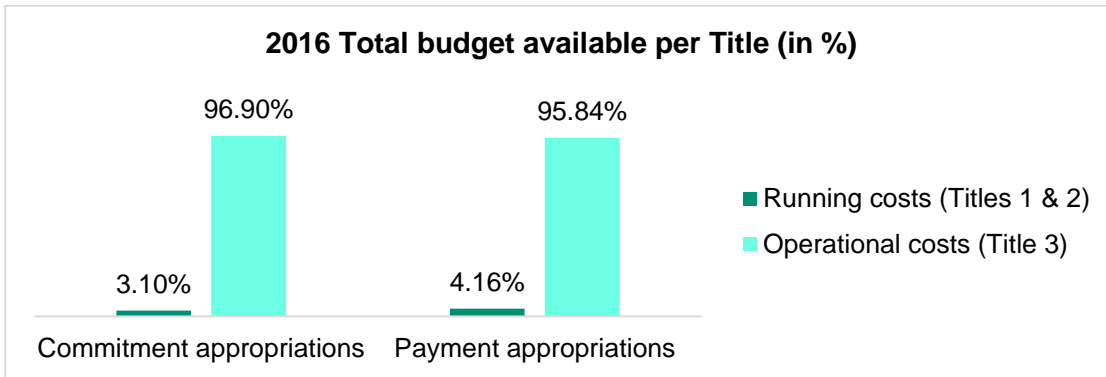
The 2016 budget was approved by the IMI2 JU Governing Board on 13 January 2016. The first budget amendment was approved by the IMI2 JU Governing Board 27 April 2016 in order to include the carry over amounts from previous year.

A second budget amendment was approved on 5 December 2016 in order to include financial contributions from Associated Partners and Other Members.

Budget 2016 in EUR'000										
	Voted budget		Carry over Amending budget no 1		Amending budget no 2		Assigned revenue*		Final budget	
	CA	PA	CA	PA	CA	PA	CA	PA	CA	PA
Revenue										
EC contribution	207 927	201 740	80 972 000	51 861					288 898	253 601
EFPIA contribution	4 740	4 740							4 740	4 740
Assoc. Partners					7 000	2 669			7 000	2 669
Other members					4 200	200			4 200	200
Total revenue	212 667	206 480	80 972	51 861	11 200	2 869			304 838	261 209
Expenditure										
Title 1	5 353	5 353		220					5 353	5 573
Title 2	4 127	4 127		1 229			29	29	4 156	5 385
Title 3	295 359	199 869		50 411			2 186	2 186	297 544	252 465
Total expenditure	304 839	209 349		51 861			2 214	2 214	307 053	263 423

*The assigned revenue shows the amounts recovered during the year from suppliers.

The graph below shows the 2016 total budget available per Titles in %.



5.2 Budget transfers

One budget transfer from Title 1 to Title 2 was made during 2016; this was below the 10% threshold. Budget transfers between chapters were authorised in 2016 which led to the following changes:

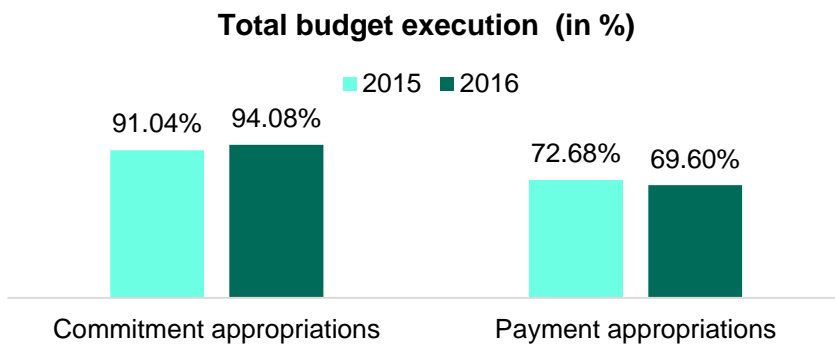
Chapter		Budget voted EUR	Budget transfer EUR	Budget after transfers EUR
11	Staff in active employment	4 893 000	- 104 000	4 789 000
13	Missions	190 000	- 90 000	100 000
14	Socio-medical structure	230 000	176 000	406 000
20	Investments in immovable property rental of buildings	660 000	21 000	681 000
21	Information Technology purchases	560 000	154 000	714 000
22	Movable property	153 000	- 143 000	10 000
23	Current administrative expenditure	123 000	10 000	133 000
24	Postage and telecommunications	68 000	- 24 000	44 000
25	Expenditure on formal meetings	158 000	- 48 000	110 000
26	Expenditure in connection with operational activities	300 000	48 000	348 000
27	External communication information and publicity	625 000	- 25 000	600 000
28	Studies	780 000	- 1 000	779 000
29	Expert contracts and meetings	700 000	26 000	726 000

5.3 Budget implementation

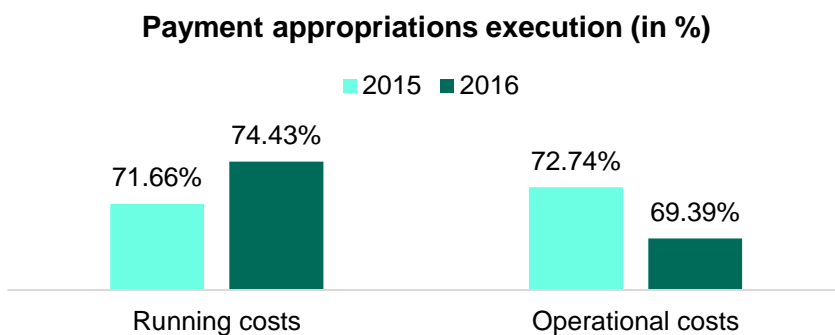
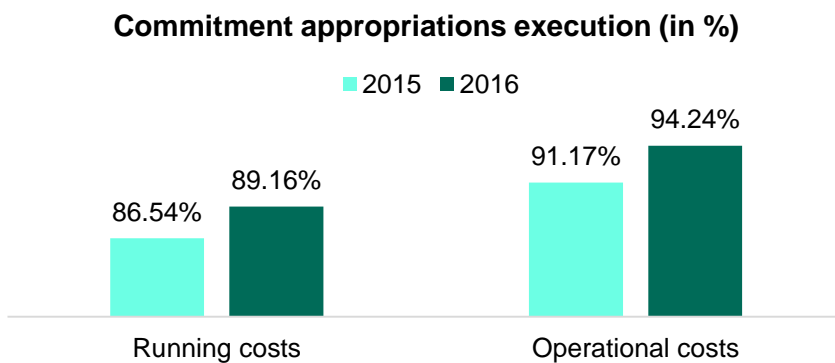
The table below shows the execution of the 2016 budget per Title in absolute amounts.

Title	2016 final budget execution per Title in EUR					
	Commitment appropriations	Execution	%	Payment appropriations	Execution	%
Title 1	5 334 540	4 707 100	88.24	5 554 850	4 648 750	83.69
Title 2	4 174 140	3 771 010	90.34	5 403 540	3 507 070	64.90
Subtotal running costs	9 508 670	8 478 100	89.16	10 958 390	8 155 810	74.43
Title 3	297 544 090	280 394 380	94.24	252 465 100	175 182 730	69.39
Total (Title 1, 2 and 3)	307 052 760	288 872 480	94.08	263 423 490	183 338 540	69.60

The graph below shows the 2016 total budget execution compared with 2015.



The graphs below show the 2016 budget execution for operational activities (project-related) and for running costs (staff and infrastructure) compared with 2015.



The performance objectives of the annual budget execution as established in the Annual Work Plan 2016 were: $\geq 95\%$ for commitment appropriations for running costs and operational costs, and $\geq 95\%$ for payment appropriations of operational costs.

The total budget execution of the commitment appropriations reached a level of 94.08 %, and of the payment appropriations a level of 69.60 %.

5.3.1 Administrative expenditure (Title 1 and Title 2)

Regarding the administrative expenditure (running costs), despite some recruitments carried in 2016, the number of staff employed at the end of 2016 was lower than the maximum authorised, resulting in lower execution than planned.

IMI continued to execute its budget applying principles of sound financial management, resulting in savings in the organisation of events, communication and administrative expenditure.

It is important to note that the EC part of unused appropriations for running costs will be made available for operational activities in the 2017 budget.

5.3.2 Operational expenditure (Title 3)

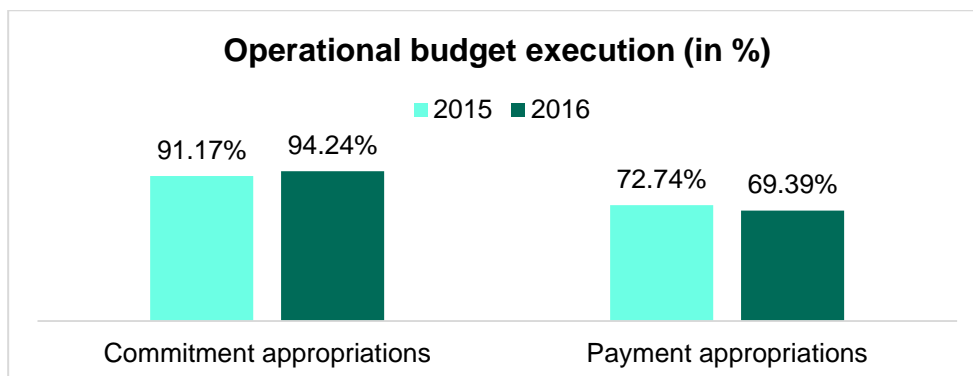
The operational budget approved for 2016 was EUR 297 544 090 in commitment appropriations (CA) and EUR 252 465 100 in payment appropriations (PA).

Budget execution of the commitment appropriations reached 94.24 % of the total budget, with payment appropriation execution reaching 69.39 %.

The commitment appropriations linked to the research agenda were consumed by Grant Agreements for projects under IMI2 – Call 3, 5 and 6 and by launching IMI2 – Calls 9 and 10. The launch of IMI2 – Call 11 (Horizon 2020) was postponed to 2017.

The payment appropriations were consumed by intermediate payments for projects from IMI1 – Calls 1–11 and IMI2 – Call 2, as well as pre-financing for projects of IMI2 – Call 3, 5 and 6.

The budgeted payment appropriations were not fully used in 2016 due to significant underspending in the Ebola+ programme, and delays in concluding Grant Agreements for projects under IMI2 - Calls 7 and 8.



The tables below indicate the operational budget execution (Title 3) per programme.

	Execution of commitment appropriations in EUR							
	Budget			Additional appropriations (carry over + assigned revenue)		Total		
	Voted budget	Execution	%	Appropriations	Execution	Appropriations	Execution	%
IMI1	-	-	-	85 530	-	85 530	-	-
IMI2	214 386 590	214 348 320	99.98	83 071 970	66 046 050	297 458 560	280 394 380	94.26
Total	214 386 590	214 348 320	99.98	83 157 500	66 046 050	297 544 090	280 394 380	94.24

	Execution of payment appropriations in EUR							
	Budget			Additional appropriations (carry over + assigned revenue)		Total		
	Voted budget	Execution	%	Appropriations	Execution	Appropriations	Execution	%
IMI1	130 448 760	109 792 160	84.16	85 530	54 520	130 534 290	109 846 680	84.15
IMI2	69 419 830	63 236 040	91.09	52 510 970	2 100 000	121 930 800	65 336 040	53.58
Total	199 868 600	173 028 210	86.57	52 596 500	2 154 520	252 465 100	175 182 730	69.39

The commitments carried forward from 2015 to 2016 included the amounts committed at the launch of Calls and the amounts committed based on grant agreements concluded.

The commitments related to Calls launched are consumed by the commitments based on the grant agreements concluded. Under the N+3 rule for PPP bodies as set out in IMI2 Financial Rules, the unused appropriations may be entered in the estimate of revenue and expenditure of up to the following three financial years.

The commitments related to Calls 7 and 8 were de-committed at the end of 2016 and, based on the N+ 3 rule as set out in the IMI2 Financial Rules, the unused appropriations will be carried over to the 2017 budget.

The table below shows the summary of commitments outstanding for operational expenditure per programme at the end of 2016.

Commitments carried forward from previous year 2015	Commitment appropriations in EUR				
	Carry forward	Commitments made during 2016	De-commitments	Payments	Commitments outstanding at end 2016
IMI1	427 949 660	-	-	109 846 680	318 102 970
IMI2	305 757 020	280 394 380	- 116 802 180	65 336 040	404 013 170
Total	733 706 670	280 394 380	- 116 802 180	175 182 730	722 116 150

5.3.3 Overview of the carry over appropriations to 2017

IMI will re-enter into the 2017 budget the unused commitment and payment appropriations from 2016.

Administrative expenditure:

- Payment appropriations of EUR 1 416 709, corresponding to the amount of commitments carried forward from the 2016 to the 2017 budget.

Operational expenditure:

- The commitments related to Calls 7 and 8 were de-committed at the end of 2016 and, based on the N+ 3 rule as set out in the IMI2 Financial Rules, the unused appropriations will be carried over to the 2017 budget. The unused commitment and payment appropriations to be carried over to 2017 budget was of EUR 134 467 173* corresponding to commitment appropriations, and of EUR 77 282 369* corresponding to payment appropriations.

	Commitment appropriations (EUR)	Payment appropriations (EUR)
Unused appropriations (operational and administrative)	*134 467 173	*78 699 078

*subject to Governing Board approval

6 IMI2 JU programmes

Multiannual budget execution as at 31.12.2016 (ongoing projects/Calls)

The table below shows the remaining obligation under signed grant agreements per Call. The amounts for IMI2 Calls 9 and 10 show the global commitment made for each Call.

Call	Commitments EUR '000	Paid EUR'000							RAL EUR '000
		2010	2011	2012	2013	2014	2015	2016	
FP7 (IMI1)									
Call 1	116,082	20,504	15,213	45,251	19,525	4,852	2,361	5,025	3,351
Call 2	85,765	14,738	28,529	3,083	9,370	14,716	6,442	2,075	6,812
Call 3	113,103	-	25,237	3,669	18,306	19,612	13,536	21,256	11,487
Call 4	97,880	-	-	26,087	7,824	17,288	7,913	23,083	15,685
Call 5	79,999	-	-	20,604	602	10,416	15,214	17,184	15,979
Call 6	125,417	-	-	5,115	19,089	4,378	8,679	10,456	77,700
Call 7	13,000	-	-	-	6,600	-	3,013	1,074	2,313
Call 8	98,733	-	-	-	40,152	-	8,111	11,769	38,701
Call 9	56,441	-	-	-	-	12,250	9,036	6,535	28,620
Call 10	6,100	-	-	-	-	-	1,952	638	3,510
Call 11	173,540	-	-	-	-	36,539	12,305	10,752	113,944
Total FP7 (IMI1)	966,060	35,242	68,979	103,809	121,468	120,051	88,562	109,847	318,103
	Paid cumulative FP7		104,221	208,030	329,498	449,549	538,111	647,958	

Call	Commitments EUR '000	Paid EUR'000						RAL EUR '000	
		2010	2011	2012	2013	2014	2015		2016
H2020 (IMI2)									
Call 1	17,630	-	-	-	-	-	2,519	-	15,111
Call 2	114,090	-	-	-	-	-	39,837	13,037	61,216
Call 3	56,060	-	-	-	-	-	2,693	19,060	34,307
Call 4	1,130	-	-	-	-	-	904	-	226
Call 5	47,477	-	-	-	-	-	-	16,377	31,100
Call 6	46,696	-	-	-	-	-	-	16,862	29,834
Call 7	-	-	-	-	-	-	-	-	-
Call 8	-	-	-	-	-	-	-	-	-
Call 9	58,328							-	58,328
Call 10	173,890							-	173,890
Total H2020 (IMI2)	515,301	-	-	-	-	-	45,953	65,336	404,013
	Paid cumulative H2020						45,953	111,289	
TOTAL FP7 + H2020	1,481,361	35,242	68,979	103,809	121,468	120,051	134,515	175,183	722,116

7 Revenues

According to the financial rules of IMI2 JU, revenues are funds made available to the Joint Undertaking by different sources to cover administrative and operating expenditure for a year and form part of the annual budget. The table below outlines the breakdown of the revenues received in 2016.

Source of revenues in EUR	2016	
	Budget	Cashed
EC contribution to running costs and operational costs	201 740 000	201 740 000
EFPIA contribution to running costs	4 740 000	3 308 610
Associated Partners contribution to operational costs	2 668 600	2 668 600
Other Members contribution to operational costs	200 000	200 000
TOTAL	209 348 600	207 917 210

The difference between the budgeted and cashed contribution from EFPIA comes from the fact that EFPIA reimburses real running costs incurred in a given year rather than paying based on the budgeted amounts. The balance is settled in the following year.

The graph below shows the IMI2 JU revenues in %.

