ERASMUS MC
TECHNOLOGY TRANSFER OFFICE

2017
ANNUAL
REPORT

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Erasmus MC
Universitair Medisch Centrum Rotterdam
Preface

It is my privilege to say a few words in the preface of TTO’s annual report 2017.

2017 has shown that TTO – notwithstanding the headwind they felt in the first half because the headcount in the BD-team was almost halved—was capable to help Erasmus MC employees (mainly scientists and doctors) to generate an impressive number of new ideas.

The growth seems to have settled at a level, that will guarantee a good flow of new inventions from Erasmus MC back to society. A good idea is not a product yet, but after the boost that Erasmus MC has given to TTO three years ago, it seems that the results are about to be harvested in the coming years.

The number of contracts being evaluated by TTO showed again a double digit growth. We are happy that so many of our employees find the way to TTO to have their contracts evaluated. A proper evaluation of contracts is critical to protect the employees and Erasmus MC and saves us from potential leakages of IP and irregular use of our knowledge and results.

The Board is curiously following the developments and we are confident that TTO will continue to support researchers and doctors of Erasmus MC to develop their ideas and inventions for the benefit of society. We hope that more and more other employees a.o. nurses and other professionals will realize that their innovative ideas can be of value, and will contact TTO for support.

Prof.dr. J.P.T.M. (Hans) van Leeuwen, Dean
Major achievements in 2017

• Quantib B.V. raised €4.5 Million for further growth
• Sensius B.V. received a loan from UNIIQ for Proof of Concept financing
• Harbour Biomed Ltd. was refinanced
• Three spin offs established
• TTO licensed out an idea that was developed by its own team
• A risk analysis was made of the critical process of TTO within Erasmus MC
• The “ValorisatieProgramma Rotterdam” was evaluated, which resulted in the continuation of the activities in “ZorgInnovaties010”
• Launch of Life Science & Health Hub in the Rotterdam Science Tower
Introduction

TTO has made further steps in establishing a well-renowned department within Erasmus MC. Of course that comes along with growing pains, and some of those will be highlighted in this year report along with the achievements of 2017.

We are a developing department, and therefore are not adverse to taking risks to improve our organization and learn from experience. One of the highlights in this respect was the continued support that we received from the PROGRESS-TT initiative supporting “growing TTO’s” into “excellent TTO’s”. Together with our coach, we have explored different options to develop our TTO into a more professional organization. A few national and international interviews and discussions have taught us where there is room for further improvements.

We have experimented with a number of possibilities, of which we kept the best initiatives and dropped those that did not deliver as expected. An example of the latter was the appointment of a Legal Secretary in an attempt to ease the workload of the legal team. However, it turned out that the tasks related to this function did not fit the needs of the team.

An example of a very successful initiative was the continuation of the Valorisation Programma Rotterdam. Not only did it result in the establishment of two start-ups, it also increased the cooperation with the Municipality of Rotterdam, who has a direct interest in supporting better care initiatives for the residents of Rotterdam and economic activity in the field of Life Science and Health Care.

In 2017, TTO together with the Control & Compliance department performed a risk analysis on the impact of the work processes of TTO to Erasmus MC as a whole. The outcome was that TTO has adequately mitigated the internal risks with a good mandate (both as a direct mandate from the Board of Directors as well as via the signature-procedure) and well described internal processes (i.e. via the Patent Regulation, Participation Regulation and Financial Conflict of Interest Regulation), but that consequential damage to Erasmus MC of not following these regulations may be substantial. The probability may be low, but the damage may be significant. The conclusion of the risk analysis was that a well-established TTO helps to lower this probability.

Another trend that we recognized in 2017, is that large companies request for longer term Partnership Agreements, in which a number of boilerplate issues (mainly concerning IP and liabilities) are agreed upon so that projects can be evaluated and established quicker with less negotiations. We concluded one such a Partnership Agreement and are in negotiations with three others.

In the 2016 annual report we anticipated that the rapid growth of TTO would level off in 2017. However, that did not happen. From a positive perspective, it shows that the services of TTO are needed and valued. However, because TTO is more visible
and present at many different levels within the organisation, our advisors are also expected to have an expert opinion on a wider range of topics, that are not necessarily directly linked to the portfolio of TTO. Although we are there to support the staff of Erasmus MC, we risk losing focus through our increasing involvement in too many unrelated TTO projects. This was one of the key challenges of 2017, and will continue to be a challenge in 2018.

A very important activity of TTO is creating internal awareness for our activities: how do we communicate our message to our internal clients? TTO is accessible to all Erasmus MC employees, although mainly scientists and doctors are using our services. Therefore, we have dedicated ourselves in creating awareness in other departments of Erasmus MC through internal awareness sessions and by joining and/or organising workshops. TTO also has the responsibility to demonstrate our capabilities to external parties, which we achieve by attending various conferences and networking events.

Next to that, we continue to actively post on our LinkedIn page, not only new technologies and aspects of our work, but also activities where TTO advisors are actively involved in. Currently, we have around 350 followers and steadily increasing.

Furthermore, TTO is involved in many regional activities and meetings, including, but not limited to:
- Medical Delta
- Innovation Quarter acquisition
- Rotterdam Partners
- ZorgInnovaties010

An overview of TTO’s activities is summarized in Table 1.
Table 1: Exposure

<table>
<thead>
<tr>
<th>Type</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal awareness sessions</td>
<td>4</td>
<td>34</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>(Inter)national visits and meetings hosted</td>
<td>5</td>
<td>7</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Conferences and Networking events</td>
<td>7</td>
<td>24</td>
<td>63</td>
<td>54</td>
</tr>
<tr>
<td>(Inter)national Presentations</td>
<td>0</td>
<td>4</td>
<td>9</td>
<td>21</td>
</tr>
</tbody>
</table>

**Internal awareness sessions**: Internal awareness sessions are those presentations that may inspire employees to use the support of TTO. In 2017 we have actively broadened our scope towards PhD students and post-docs (the faculty of the future), and within the medical curriculum. We will continue these internal awareness sessions until all Erasmus MC employees are familiar with the services provided by TTO.

**(Inter)national visits and meetings hosted**: When (inter)national visitors visit TTO, they mainly visit our Incubator in the Rotterdam Science Tower (RST), but there is also increasing interest in our Life Science and Health Hub since its opening in early 2017. The combination of all activities in the RST on the different floors makes it a very attractive spot for innovation, which attracts a lot of (inter)national attention.

**Conferences and Networking events**: The visibility of TTO has increased in the past year, resulting in an increase in invitations for TTO to attend both internal and external events. These events are important, mainly because they help us to connect with our environment, expand our network and to link us to people who we would normally not meet.

Furthermore, as Erasmus MC is a partner organisation of EIT Health (https://www.eithealth.eu/), TTO was requested to organise and support three events in the EIT-programmes, which included the Launch Lab, Living Labs, and Local Training.

**(Inter)national Presentations**: TTO is increasingly perceived as an active player in the field as our presence at conferences are increasingly requested, not only as participants, but also to share our experiences and activities through presentations. Indeed, the PORGRESS-TT support has given us an enormous boost to further professionalise our TTO.
Subsidies

- Octrooifonds (‘Patent Fund’) is an Erasmus MC fund (€ 100,000) for internal investments in Intellectual Property. The budget for the Octrooifonds comes from the Licentiefonds (see below) and is meant as a subsidy that covers 50% of the initial costs for a patent application. When a patent is licensed or leads to revenues for Erasmus MC, this fund is reimbursed. The number of new patent applications has increased enormously leading to an increased demand for investments from the Octrooifonds. Therefore, the budget is insufficient, resulting in a formal request to the Board of Directors to double the budget in 2018.

- Licentiefonds (‘License Fund’) is an Erasmus MC fund collecting any and all income (royalties, milestone payments, etc.) related to technologies and know-how of Erasmus MC that are currently out-licensed. When collected, the ‘fair distribution’-rule (the so called 40-40-20 rule) is executed following the Patent Regulation of Erasmus MC. This fund is administrated by TTO, but controlled by the Dean. Its income has previously been used for special projects, such as funding of the Erasmus MC Incubator, our participation in UNIIQ and Swanbridge (see below), and also some fundamental research programmes.

- EFRO I is a subsidy allocated by the European Fund for Regional Development. Although the subsidy period was finalized by end of 2015, Erasmus MC still has the obligation to maintain the Incubator until at least September 2022. TTO executes the management and administration of the Incubator.

- EFRO II is a subsidy allocated by the European Fund for Regional Development. In 2017, we drafted a grant application for the support of start-ups in the very early stages. This proposal aimed to breach the evident gap between the “entrepreneur with a good idea” and the actual definition, description and set up of a business plan, all of which are important for the pitch document used to reach out and obtain investments. The ‘Kansen voor West’ authorities supported our grant application. However, the deadline for submission was delayed several times in 2017, allowing us only to formally apply for this subsidy by the end of February 2018.

- “ValorisatieProgramma Rotterdam” (VPR) is a consortium of Erasmus University Rotterdam, InHolland, Hogeschool Rotterdam, Albeda College, Medical Delta Multiplier (MDM) and Erasmus MC, that ran from 2012 until 2017 with the goal to disseminate knowledge from the knowledge institutes to society. The Ministry of Economic Affairs subsidized the ValorisatieProgramma Rotterdam with €5 million for the first four years (2012 - 2015).

Although the Board of Erasmus MC was responsible for this program, TTO was requested to define and implement the activities that the Board had accepted and agreed upon.
These activities spanned from scouting and screening up to commercialization of innovations in care (also known as ‘low-tech innovations’). The Board of Erasmus MC requested TTO to acquire additional resources to maintain the program. In 2017, we managed to team up with the Municipality of Rotterdam and received a subsidy to finance the continuation of the activities under the name ‘ZorgInnovaties010’ (‘Care Innovations 010’). The impact of ZorgInnovaties010 is already visible as two out of the three spin-offs that were established in 2017 came from this line of Business Development.

- PPP (TKI) allowance is a subsidy program initiated by the Netherlands Enterprise Agency through Health-Holland, aimed at stimulating private public collaborations. This program allows scientists to obtain additional funding based on the contribution of a private partner to a collaboration. A condition for the additional funding in this program is a collaboration agreement with, inter alia, an intellectual property clause that is fair for both parties. TTO actively screens contracts, informs scientists about the existence of the program and structures the collaborations to make them eligible for the allowance. In 2017, we successfully applied for € 1.321.438 TKI-allowance (see also below)
TTO Teams: Business Development

2017 started with some big challenges for the Business Development (BD) team due to an unexpected decrease in the number of FTE. We ended 2016 with 6.9 FTE, which reduced to 3.9 in February 2017 due to pregnancy leave, discontinuation of contracts (project funded) and a resignation. From July 2017 the team was back to sufficient strength at 5.8 FTE. The average number of FTE available in 2017 was 5.2.

While we started with reviewing and optimizing our processes in 2016, we continued our efforts in 2017. As a result, the total relative output of the (smaller) team in 2017 is comparable to that of 2016 (approx. 16.4 new Invention Disclosures (IDs) per available FTE).

However, as indicated in Table 2, many of the KPIs for 2017 show a decrease compared to 2016. The lower number of new IDs is directly related to the number of BDs available for evaluation and intakes. Thus, the lower number of new IDs directly influenced the number of signed Invention Disclosure Forms (IDFs). The lower number of Patent Applications might be the result of a more stringent evaluation process, which we will need to monitor closely to ensure that the requirements are not too stringent and thus result in missing opportunities.

The number of Licenses and spin-offs has increased compared to 2016. This is to be expected based on the higher number of IDs and IDFs, and the time needed from evaluation to closing a deal, which will typically take an average of 3-5 years.

After a very rapid and significant increase in Added Value in 2015 and 2016, we see a sudden drop in 2017. An important contributing factor to the Added Value has been Clinical Trial budgets that are (re)negotiated. After demonstrating success in these type of contracts in previous years, we noticed that our internal customers contact us at a much earlier stage. As such we can no longer speak of added value (as no value was determined upfront). As for the TKI-Program, it is a very complex but interesting subsidy from Rijksdienst voor Ondernemend Nederland (RVO) (see below) which TTO has taken up, we also see these results as Added Value from TTO to Erasmus MC.

Since 2015, we have seen a steady decrease in Royalty Income. This is partially due to older contracts ending and the lower number of contracts that have been executed in 2013 and 2014. The expected lag between signing a contract and the generation of revenues, caused by the necessary time to develop a product based on an invention before sales to grow to a significant number, means that we do not yet see much revenue coming in from the contracts that have been signed since 2015.
Table 2: TTO-Business Development KPIs

<table>
<thead>
<tr>
<th>Key Performance Indicator</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>Increase '16-'17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invention Disclosures (IDs)</td>
<td>40</td>
<td>96</td>
<td>113</td>
<td>85</td>
<td>-25%</td>
</tr>
<tr>
<td>IDFs Signed</td>
<td>12</td>
<td>23</td>
<td>34</td>
<td>29</td>
<td>-15%</td>
</tr>
<tr>
<td>Patent Applications</td>
<td>9</td>
<td>14</td>
<td>20</td>
<td>11</td>
<td>-45%</td>
</tr>
<tr>
<td>Patents Granted</td>
<td>4</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>*</td>
</tr>
<tr>
<td>Total Patents in Portfolio</td>
<td>113</td>
<td>61</td>
<td>80</td>
<td>82</td>
<td>*</td>
</tr>
<tr>
<td>New Licenses</td>
<td>8</td>
<td>17</td>
<td>11</td>
<td>13</td>
<td>18%</td>
</tr>
<tr>
<td>Royalty Income</td>
<td>€440.00</td>
<td>€507.87</td>
<td>€392.62</td>
<td>€278.14</td>
<td>*</td>
</tr>
<tr>
<td>Additional Added Value</td>
<td>NA</td>
<td>€3.135.770</td>
<td>€11.515.425</td>
<td>€3.006.677</td>
<td>*</td>
</tr>
<tr>
<td>Spin-off companies</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>200%</td>
</tr>
<tr>
<td>Total agreements reviewed</td>
<td>720</td>
<td>979</td>
<td>1171</td>
<td>1503</td>
<td>28%</td>
</tr>
</tbody>
</table>

Table 2 shows the general outcome of the Key Performance Indicators of TTO. See text for explanation; *: calculating the difference year-on-year does not mean anything, and therefore this number is not calculated.

Figure 1: Distribution of Business Development activities since 2014 per Theme
Figure 1 illustrates how many activities TTO has initiated per theme since 2014. In previous annual reports, we have presented data in relation to the different themes, number of employees and the number of new IDs per theme. One of the recurring conclusions was that the relatively small theme “Biomedische Wetenschappen” usually represented a large portion of the new IDs in any year.

Figure 1 gives a new representation of the results and shows that the number of ideas per theme in any given year is difficult to predict. Although some themes are quite stable in the number of new ideas (e.g. Hersenen en Zintuigen, Thorax and to some extent Daniel den Hoed), others show a steady increase (e.g. Sophia, Spoed Peri-operatief en Intensief en Gezondheidswetenschappen). This increase might be explained by the improved visibility of TTO and the trust that has been built up since late 2014. The sudden rise and drop over time for the themes Biomedische Wetenschappen, Diagnostiek en Advies and Dijkzigt are difficult to explain. For Dijkzigt, it might be related to a backlog in sharing ideas, or 2016 could simply have been a very successful year. The preparation for the move to the new Erasmus MC Hospital in 2018 may also have an impact as this move has major impact for many of the care-related departments that are mainly brought together in Theme Dijkzigt. As a result, less attention and time is available for development of new inventions.

The rise and drop seen for Biomedische Wetenschappen and Diagnostiek en Advies can be partially explained by increased awareness and a backlog in 2015 with a residual effect in 2016. However, the developing trend in 2017 will be monitored closely in 2018. To remedy the situation, we will work on revisiting the departments to ensure they are aware of TTO.

**Promotion of licensing opportunities**

We have continued to actively promote our technologies digitally on the EBD partnering platform, Flintbox and the TTO website, as well as in person via conferences such as the Bio-events. Obviously, we also actively search for and reach out to potential partners that could be a good match with an invention.

We have also started exploring how we can use LinkedIn to promote these inventions and create further traction in the licensing process.

**Follow-up on license agreements**

With our steadily increasing licensing portfolio, the management and follow-up is becoming more time consuming. In the past year, we have invested a part of our time in the clean-up of the agreement overviews and in defining a clear process for the registration and follow-up of license agreements. This process is not finalised yet, but we see that our administration is becoming more professional and therefore more easily accessible.
As mentioned, we expect that the Royalty income will stabilize or may start to increase in 2018 and that it will steadily grow from there onwards.

Types of licenses signed

A total of thirteen new license agreements were entered into in 2017. These licenses show the diversity of the technologies that TTO is transferring to the market as they include (amongst others): Software, mouse models, cell lines, questionnaires, know-how, research tools, biomarkers and a potential biological therapy.

Three of these licenses were the basis for the creation of new companies.

Proof-of-Concept:

UNIIQ

UNIIQ was founded in 2016 by Erasmus MC, Leiden University, TU Delft and Innovation Quarter, and was granted a European grant. The fund, totalling € 22 million, invests in companies in the proof-of-concept phase in order for them to overcome an important hurdle towards traditional venture capital. In 2017, UNIIQ signed 9 investment deals, totalling € 2.7 million in commitment. This brings the total number of investments for UNIIQ to 16.

In 2017, one spin off from Erasmus MC (Sensius BV) was granted a UNIIQ-loan.

Swanbridge Capital

Swanbridge Capital is an early stage venture capital fund, specifically aimed at the Life Sciences sector. Erasmus MC is one of the largest shareholders in the fund. Swanbridge Capital advances early stage technologies and companies to the next phase through a combination of equity-investments and active support for the company.

Swanbridge Capital made investments into two companies in 2017.
Legal

Legal support related to research and valorisation

The legal counsels of TTO provide the guidance and support for Erasmus MC staff in contacts with third parties, related to scientific research activities and valorisation of the outcome of research. Furthermore, advice is provided regarding research collaboration with other research institutions and commercial parties all over the world. Such activities also include assistance during the establishment of international (subsidized) consortia, usually with large numbers of third parties. The team focusses on the field of intellectual property law and handles conflicts with industry or claims from third parties, all related to research. In contract negotiations, the legal counsels protect the interests of Erasmus MC and especially the scientific freedom (independence) of the Erasmus MC scientists. This includes the freedom to publish all outcome of scientific research.

Figure 2: The dark blue bar indicates the number of agreements reviewed by TTO’s Legal team in 2017 per Theme. The graph line indicates the total number of FTE per Theme, and the light blue bar indicates the number of agreements that one would expect relative to the number of FTE per Theme.

Figure 2: Distribution of Legal activities per Theme
The services of the legal counsels are available for the entire Erasmus MC. There is however a difference in the number of requests that TTO receives for legal assistance per department. This difference may be caused by the specific nature of a department; e.g. Theme Sophia is in fact an entire children’s hospital and cannot be compared with a smaller theme such as Hersenen & Zintuigen (H&Z ‘Brain and Senses’).

The legal staff of TTO at the end 2017 consisted of 8,31 FTE compared to the 8,35 FTE of 2016. The coordinator of the legal counsels was partially (approximately 0.2 FTE) entrusted with the training of new staff and the coordination of the work of the group.

Figure 3: Growth of number of contracts 2014-2017

Steady growth of the number of request for advice

In the past years, the legal team has dealt with a steady growth of the number of requests for assistance. This tendency also continued during 2017 (see Figure 3).

Figure 3: In this picture the total number of registered Advice and Agreement evaluation requests are represented.
The growth in the total number of requests is partially caused by the fact that researchers are becoming more conscious of the necessity to construct (oral) arrangements with third parties in a proper agreement, so as to avoid future problems. At the same time, the number of business developers within TTO has grown, resulting in increased requests for agreements. The legal counsels and business development managers try to work closely together in all negotiations to get to the best possible results for Erasmus MC. In this way, we avoid that companies might “shelve” Erasmus MC inventions and we aim at making all improvements available to society (patients) as soon as possible.

In spite of the growth of the number of legal counsels within TTO, it is still necessary to use the services of an external flexible workforce (external legal counsels) to cover periods of longer response time. The justification for this flexible workforce is linked to a number of time-consuming projects, e.g. handling of conflicts with external parties and Horizon2020 coordinator positions. The position of coordinator for such projects requires a lot of extra attention from our legal counsels due to the often time-consuming negotiations with a number of international collaborators. As a consequence, other requests are delayed, resulting in slowed response times.

Figure 4 gives an indication of the steady growth of the activities of the legal counsels of TTO. While we used to use an Excel sheet to keep track of the contracts in our portfolio and the contracts being evaluated, with this enormous growth over the past few years, we needed to introduce something better. With a software company, we developed a tool that not only automatically assigns a new request from a scientist to the legal counsel with the lowest workload, but also monitors the individual preferences and expertise of the legal counsels. Next to this, the system also provides all kinds of management information that allows us to understand the workflow better. As the system was introduced over the course of the year, we cannot publish any of these results in this year report yet. Next year we will be able to give a better insight in the Legal workflow. The system is now also evaluated for implementation at Juridische Zaken (‘Legal Department’) to handle all non-IP related legal requests, and the Research Development Office (RDO) is implementing an adapted version of this system for all grant applications.
Table 3: Production of TTO Legal team

<table>
<thead>
<tr>
<th>Contract type</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>Increase '16-'17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial Agreements</td>
<td>132</td>
<td>184</td>
<td>214</td>
<td>320</td>
<td></td>
</tr>
<tr>
<td>Material Transfer Agreements</td>
<td>79</td>
<td>107</td>
<td>198</td>
<td>205</td>
<td></td>
</tr>
<tr>
<td>Confidentiality Agreements</td>
<td>82</td>
<td>117</td>
<td>141</td>
<td>141</td>
<td></td>
</tr>
<tr>
<td>Grant/Consortium Agreements</td>
<td>106</td>
<td>122</td>
<td>95</td>
<td>198</td>
<td></td>
</tr>
<tr>
<td>Research Agreements</td>
<td>69</td>
<td>82</td>
<td>130</td>
<td>140</td>
<td></td>
</tr>
<tr>
<td>- inter-institutional</td>
<td>-</td>
<td>-</td>
<td>59</td>
<td>85</td>
<td></td>
</tr>
<tr>
<td>- Commercial</td>
<td>-</td>
<td>-</td>
<td>71</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td>Consultancy Agreements</td>
<td>46</td>
<td>68</td>
<td>56</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Data transfer/database/processor's agreements</td>
<td>-</td>
<td>-</td>
<td>32</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>Other agreements *</td>
<td>206</td>
<td>299</td>
<td>305</td>
<td>414</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>720</td>
<td>979</td>
<td>1171</td>
<td>1503</td>
<td>28%</td>
</tr>
</tbody>
</table>

Table 3 shows a broad overall result of the production of the legal team. The overall production grew with 28.1 percent but these numbers differ a bit for different subdivisions. There is no conclusive reason for these differences, but it could be due to the categorization that scientists are requested to tick when uploading documents for evaluation.

* “Other agreements” are for example letters of intent/commitment, service agreements, speaker agreements and amendments to existing contracts.
Figure 4: The Schedule of Contract Types does not cover all work of the legal group since a number of tasks, such as providing teaching and awareness sessions are not registered in the digital administration system that is shown in this schedule.

While the total number of contracts has grown 28.1% in 2017 (Table 3), there are a few categories in this Figure that need extra explanation:

Grant Agreements: with the establishment of RDO the number of grant applications have risen quite rapidly, and with that also the number of grant agreements.

Advice: With the introduction of our software tool the category “Advice” is used more frequently as the category “Other” was dropped. There could be a degree of over-reporting in this category since we find some scientists still do not know in which category a contract should be uploaded in the system, and therefore use this category. This needs to be fine-tuned.

Clinical Trial Agreements: Our institute is involved in a strong growing number of clinical studies; the Clinical Trial Agreements are a separate category of contracts that should protect both the interests of the patients as well as the scientific freedom and integrity of Erasmus MC staff.

The stronger the appreciation for TTO, the more scientists will involve us, also with the smaller and obvious contracts. Especially for clinical trials and consultancy agreements, scientist feel they should not automatically accept the draft agreements industry is offering them.
Privacy issues and the new General Data Protection Regulation

The EU General Data Protection Regulation, which shall enter into force as from 25th May 2018, resulted in a large number of questions and issues especially relating to the use of (patient) materials and data by Erasmus MC scientists in collaboration with third parties, e.g.:

- Does the GDPR contain exceptions for biobanks?
- What is the relation between data protection and privacy?
- How is “anonymized” defined in the new GDPR?
- How is “pseudonymisation of data” defined in the new GDPR?
- Can biobank use “broad consent” under the new GDPR?
- Does the new directive also apply to collaborations with the United States of America?
- Shall consent obtained under the current directive remain valid under the new GDPR?

Education and information

The Legal team of TTO also creates awareness for the activities it undertakes and how it can serve the research and clinical community within Erasmus MC. In this context, TTO organizes workshops and lectures for different audiences. During 2017 the following programs were organized:

- We continue to provide short presentations in the context of the BROK course several times per year. This presentation focuses on clinical trial agreements and the potential evaluation of results. It provides some guidance in evaluating a clinical trial agreement and what the impact of results may be from the intellectual property standpoint; and how the involvement of TTO can help the clinical community in facilitating assessment of clinical trial agreements.

We have experienced that more researchers approach TTO to discuss results (some resulting in new IDFs) soon after they have attended this course.

- TTO also continues to lecture, for the third year, in the minor Med School for Technical Students. This lecture entails a full afternoon in which students get acquainted with the concept of Intellectual Property and its impact from the societal and economic perspective. The lectures inform the students how to evaluate IP potential for further valorisation in any research organization; but always in cooperation with TTO.

The audience finds the lectures valuable and thus, TTO is invited each year to give this lecture. We believe
that early awareness is of vital importance because these students may become members of the research community at a later stage.

- In 2017, TTO also continued with its roadshow, including several department presentations and a special lecture for the Master Students, which serves to create awareness in understanding intellectual property and the role of TTO.

With regard to the training of our own staff, some legal counsels of TTO have participated in courses and training activities, which includes e.g. participation in the ASTP and LES courses as specialized forums that provide our personnel insight in best-practices in the field and supports networking among their peers.

Furthermore, TTO has initiated a number of in-house courses on specific legal topics. Such courses were also open for interested participants from other departments (e.g. Juridische Zaken and RDO). By providing in-house courses, which are often provided free of charge by external legal specialists from our own network, we are able to choose our own topics for training and save costs at the same time. Finally in 2017, TTO personnel was also invited to participate as a guest lecturer in the LES licensing course on November 15, in Leuven, Belgium; and as a member of the round table discussions of the IP Forum conference between April 14-16 in Augsburg, Germany.
**Paperless office, digital administration and archive**

Although much of the work of TTO is already largely paperless for a number of years, the digital workflow and archiving system was improved after the introduction of the customized software. Among other things, the system provided the possibility for TTO staff to work—simultaneously on files with colleagues and it provides a digital archive with an appropriate search option. Furthermore, it automatically provides our clients with file numbers and information regarding the status of their file and the expected response time.

TTO participated in an informal working group (secretariat of the Executive Board, IT, Purchase, and TTO) that explored the possibilities of setting up a central archive for all contracts and other type of arrangements that are concluded by Erasmus MC with third parties. Although this is not part of the main activities of TTO, we regularly have to deal with the constraint of having no central Erasmus MC archive. In view hereof, we feel that this issue is of major importance and we are willing to contribute to the discussions and the exploration of the possibilities of setting up a central contract register. The work will continue in 2018.

**In-house TTO attorney at law**

Since September 2016, we have an in-house attorney-at-law working at TTO. This enables us to make use of specialized knowledge in the field and to provide additional services to our in-house clients. In certain matters, our in-house attorney collaborates with external attorneys where matters guidance and main activities are to be performed by our in-house attorney to reduce the costs.

In 2017, more people within Erasmus MC have discovered and made use of this service. Trademark infringements and a problem with a patent registration was settled in an efficient manner and employees of Erasmus MC was guided in how to handle (other) disputes, i.e. in case of default on payments and/or delivery of materials in relation with research, and regarding (possible) IP infringements. Also, contractual issues relating to termination and advice on problems relating to the contract negotiation process have been handled by our attorney.

In these matters, possible infringements have been evaluated and advice on the approach, including setting up accompanying strategies, was provided as well as assistance in drafting an agreement (i.e. quitclaims and a settlement agreement), formal notices and a subpoena.

In 2018, we shall proceed in the same manner and will not hesitate to take legal proceedings, especially due to external attorney fees. This way, we aim to secure the rights of Erasmus MC, protect its trademark, support research and negotiation processes at lower costs.
Erasmus MC Holding

Erasmus MC Holding B.V. is fully owned by Erasmus MC and manages Erasmus MC’s participations in subsidiaries, which are related to:

- knowledge commercialization;
- care;
- and/or externally financed projects.

The goal of Erasmus MC Holding B.V. is to create and support the set-up of Erasmus MC subsidiaries. This support consists of management, financial and fiscal advice, consultancy and access to specialized facilities. Erasmus MC Holding B.V. was founded on December 31st 2003 and ultimo 2017 holds, directly or indirectly, participations in 30 subsidiaries (Table 4).

In 2017 the Holding was split into two subholdings due to the ability of managing the participations better: “Erasmus MC Zorg Holding B.V.” and “Erasmus MC O&O Holding B.V.”, and the participations were divided based on their main activity.

The tasks of Erasmus MC Holding B.V. comprise of:

- Encouraging and advising on entrepreneurship within Erasmus MC (for Erasmus MC spin-offs in collaboration with TTO). This service includes the possibilities of financial participation;
- Facilitate and support on the setup of businesses;
- Risk management for Erasmus MC and support for governance structures on large commercial projects and collaborations (non-spin-offs).

### Table 4: Overview of all participations of Erasmus MC Holding B.V. ultimo 2017

<table>
<thead>
<tr>
<th>PARTICIPATIONS</th>
<th>% OWNERSHIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>2Move Implants B.V.</td>
<td>5</td>
</tr>
<tr>
<td>Cavadis B.V.</td>
<td>1,52</td>
</tr>
<tr>
<td>Erasmus Biomedical Fund B.V.</td>
<td>32,62</td>
</tr>
<tr>
<td>HBM Holdings Ltd.</td>
<td>9,7422</td>
</tr>
<tr>
<td>HollandPTC B.V.</td>
<td>33,33</td>
</tr>
<tr>
<td>Regionale Ontwikkelingsmaatschappij InnovationQuarter B.V.</td>
<td>0,816</td>
</tr>
<tr>
<td>Erasmus MC O&amp;O Holding B.V.</td>
<td>100</td>
</tr>
<tr>
<td>abcdeSIM B.V.</td>
<td>41,9</td>
</tr>
<tr>
<td>Erasmus MC Ameland B.V.</td>
<td>100</td>
</tr>
<tr>
<td>Erasmus MC Diabetesstation B.V.</td>
<td>78,4</td>
</tr>
<tr>
<td>Erasmus MC Schiermonnikoog B.V.</td>
<td>100</td>
</tr>
<tr>
<td>Erasmus Pharma B.V.</td>
<td>100</td>
</tr>
<tr>
<td>Eurza Arbo B.V.</td>
<td>100</td>
</tr>
<tr>
<td>MI&amp;EUR B.V.</td>
<td>100</td>
</tr>
<tr>
<td>Nanod4Therapy B.V.</td>
<td>64</td>
</tr>
<tr>
<td>Neurasmus B.V.</td>
<td>100</td>
</tr>
<tr>
<td>Quantib B.V.</td>
<td>25,5</td>
</tr>
<tr>
<td>Sophia Research B.V.</td>
<td>100</td>
</tr>
<tr>
<td>Swanbridge Capital B.V.</td>
<td>37,04</td>
</tr>
<tr>
<td>Thoraxcentrum Research B.V.</td>
<td>100</td>
</tr>
<tr>
<td>UNIIQ B.V.</td>
<td>0,9615</td>
</tr>
<tr>
<td>ViroNovative B.V.</td>
<td>100</td>
</tr>
<tr>
<td>Erasmus MC Zorg Holding</td>
<td>100</td>
</tr>
<tr>
<td>Apotheek A15 Holding B.V.</td>
<td>50</td>
</tr>
<tr>
<td>CBT Rijnmond B.V.</td>
<td>50</td>
</tr>
<tr>
<td>DermaHaven B.V.</td>
<td>100</td>
</tr>
<tr>
<td>Geboortecentrum Sophia Holding B.V.</td>
<td>50</td>
</tr>
<tr>
<td>International Patient Center</td>
<td>33,33</td>
</tr>
<tr>
<td>Poliklinische Apotheek Erasmus MC B.V.</td>
<td>100</td>
</tr>
<tr>
<td>Travelclinic Erasmus MC B.V.</td>
<td>100</td>
</tr>
</tbody>
</table>
Incubator

The majority of the Erasmus MC Incubator’s activities are related to supporting Erasmus MC’s start-up companies by offering affordable laboratory- and office space in our Incubator in the Rotterdam Science Tower (RST), a small subsidy for advice, as well as access to the knowledge, network and expertise of TTO and Erasmus MC.

The Erasmus MC Incubator currently houses four companies (one new in 2017, Sensius BV):

Skyline DX BV
www.skylinedx.com

Quorics BV
www.quorics.nl

RiverD International BV
www.riverd.com

Sensius BV
www.sensius.biz

In 2017, the TTO Incubator team worked on a proposal to apply for the EFRO II subsidy to support start-ups when developing a viable business plan, since it is evident that there is still a significant gap between a good idea and a good pitch for investors.

The ‘Kansen voor West’ authorities support this initiative and our grant application. Deadline for applying will be February 2018.

As from 2012, the RST became a real hotspot in the region. National and international delegations came to visit the still growing community in and around our Incubator and RST. The increase of visits to the RST is also reflected in the role TTO plays to position the Incubator in the Rotterdam health innovations field.
Life Sciences & Health Hub

In 2016, we took the initiative, together with the Municipality of Rotterdam, Erasmus Centre for Entrepreneurship and LIFE010 consortium, to create the Life Sciences & Health Hub (LS&H Hub). The LS&H Hub is on the 9th floor of the RST and is a welcome addition to our Incubator. It houses start-up companies in the healthcare sector that only need office space.

The Municipality of Rotterdam supported this initiative by subsidizing the setup of the LS&H Hub.

On February 23, 2017 we officially launched the LS&H Hub under great interest of more than 350 people. The LS&H Hub is increasingly creating a community where parties working in the LS&H field can network with each other.

Impact LS&H Hub in 2017:

- 80+ events/ delegations/ meetings
- Housing of 13 LS&H companies
- Creating 60 new jobs
- 500+ students involved
- 70+ seniors involved
- 200+ matches care companies & start-ups
- 26 connected Hub-partners
- 12 Mio available proof of concept financing
- 50+ Erasmus MC scientist involved
- 3 successful EIT Health event
Table 5: Overview of Financials

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erasmus MC contribution to TTO</td>
<td>€ 710.349</td>
<td>€ 756.132</td>
<td>€ 876.600</td>
<td>€ 1.176.887</td>
</tr>
<tr>
<td>Licensing Income</td>
<td>€ 440.000</td>
<td>€ 507.865</td>
<td>€ 392.624</td>
<td>€ 278.137</td>
</tr>
<tr>
<td>WBSO Income realized for Erasmus MC</td>
<td>€ 502.745</td>
<td>-</td>
<td>-</td>
<td>€ 476.373</td>
</tr>
<tr>
<td>Additional Added Value</td>
<td>-</td>
<td>€ 3.135.770</td>
<td>€ 11.515.425</td>
<td>€ 3.006.677</td>
</tr>
<tr>
<td>Total added value for Erasmus MC</td>
<td>€ 232.396</td>
<td>€ 2.887.503</td>
<td>€ 11.031.449</td>
<td>€ 2.107.927</td>
</tr>
</tbody>
</table>

Table 5 shows the total overview of TTO’s financials in 2017.

“Total added value for Erasmus MC” is calculated as “Licensing Income” + “Additional Added Value” - “Erasmus MC Contribution”.

“Additional Added Value” is the added value due to (re)negotiating of contracts or to better budgeting. By offering our economic and business techniques, TTO Business Development Managers are able to add value to previous versions of budgets. The difference between the original budget and the new budget is calculated as “Additional Added Value”. The additional cash revenue to Erasmus MC research derived from the TKI scheme, is also labelled as “Additional Added Value”.

In multiple ways, TTO has assisted in the achievement of financial returns in innovation and collaboration for Erasmus MC. Traditionally, TTO’s main source of financial return came from licensing income. This income is highly volatile and often takes many years to develop after out-licensing. Over the past few years, TTO has been actively involved in other activities that support financial return. TKI, as previously stated, was managed by TTO since 2016 and yielded a significant financial cash return to Erasmus MC Research groups, totalling €1.321.438. This return could be increased by approximately €1.000.000, as part of the application is pending. Due to the operational process of TKI, final results on this will be available end of June 2018. As this income is not guaranteed, this is not included in the numbers.

Erasmus MC TTO has also assisted many departments (both research and clinically oriented) with optimization of their returns in industrial collaboration. By offering support in ongoing negotiations into MTA’s, CTA’s and other collaborations, TTO managed to obtain an increase in total funding for Erasmus MC of €1.208.866. Increasingly, TTO is meeting with departments requesting assistance before first negotiations occur. Especially departments that have previously collaborated with TTO are requesting our assistance more and more. As more departments will take such an approach, we expect that our added
value will decrease, because the involvement of TTO from the beginning of negotiations will not be considered as added value.

2017 also saw the finalization of the WBSO scheme for Erasmus MC. Due to alterations in the terms and conditions of this tax reduction regulation, Erasmus MC will no longer be able to apply for this tax reduction. After extensive conversations with both RVO and the Dutch tax authorities, Erasmus MC was awarded a total of €476,373 in WBSO tax rebate. TTO has managed WBSO for Erasmus MC for over 10 years, yielding a multi-million euro rebate. From 2018 onwards, Erasmus MC will definitively no longer be able to apply for WBSO.

In total, TTO was responsible for €3,006,677 in Additional Added Value. This is best defined as the financial return from activities other than licensing, equity divestment and IP transfer. Although the total amount of Additional Added Value is lower than in 2016, the income is much more structured. In 2016, one set of industrial collaborations saw added value of €10+ million. By increasing the number of sources for Additional Added Value, fluctuations in outcome will be limited, creating a stable financial return for Erasmus MC.

Spin-offs

This chapter focuses on certain achievements obtained by means of close collaborations between the different teams of TTO.

**Orthas BV**

Orthas has developed the ScolioCase. This product enables an earlier diagnosis of scoliosis, a disease that occurs in 3% of children, with a cardboard phone case combined with a user-friendly app. Parents can use the ScolioCase so that patients can receive adequate treatment and thereby reducing the amount of spinal surgery in children.

TTO provided Orthas know-how and a copyright license to commercialize the ScolioCase.

**Numeric Holding BV**

Erasmus MC has a novel patented invention in the field of anti-ageing and senescence-related diseases to reverse or delay the ageing processes. This invention offers potential therapeutic strategies to senescence-related diseases, such as oncology, osteoarthritis, diabetes and other disease indications. Erasmus MC has signed an exclusive license agreement with Numeric Holding B.V., which is currently in discussion with potential investors to further develop the product, using our exclusive ageing preclinical mouse models, also owned by Erasmus MC. The FOXO4 peptide has convincing in vitro and in vivo results in reversing the ageing process and has attracted worldwide attention in exploring the application of FOXO4 peptide for other ageing-related therapeutic indications.
Mateum BV

Mateum has developed software that provides insight into the planning and monitoring of hospital care in home situation of respiratory patients. This is a platform for monitoring patients, effective planning and logistics of home visits tailored to individual patient depending on hospital initiated care.

TTO provided Mateum with a license to commercialize the platform.
TKI Program

The TKI-Program, commonly referred to as the TKI Grondslag, is an allowance that was established by the Rijksdienst voor Ondernemend Nederland (RVO) and Health Holland to aid Top-consortia for Knowledge and Innovation (TKI) in the Netherlands through funding for their collaborative projects with private partners. The fund aims to match the collective private income of Erasmus MC from these collaborative projects by up to 25% for a given year. Although this is the predicative match for the collective private income, this percentage varies annually, is solely determined by Health Holland and RVO, and becomes only known to Erasmus MC once the application is approved. The funding secured from a successful PPP (TKI) Program application will be available to Erasmus MC only for the use of requesting funding for new projects through the PPP Project Allowance. The PPP (TKI) Program and PPP Project Allowance is therefore a complex, multi-faceted and labour-intensive regulation, with a lot of essential interaction, both internally and with Health Holland.

In 2017, TTO created 1.0 FTE for the management of the PPP (TKI) Program and PPP Project Allowance. This resulted in a marked increase in the TKI-results. In total 1648 projects were identified by TTO (Table 6) for all ongoing projects within Erasmus MC for 2016. The application process commenced according to strict criteria set forth by Health Holland and RVO. This resulted in 585 projects that were considered suitable for Erasmus MC’s application in terms of their funding sources.

Table 6: TKI-Program contract screening results 2017

<table>
<thead>
<tr>
<th>Type</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of contracts received</td>
<td>1684</td>
</tr>
<tr>
<td>Number of projects not eligible for funding</td>
<td>1099</td>
</tr>
<tr>
<td>Total number of projects evaluated</td>
<td>585</td>
</tr>
<tr>
<td>Percentage of projects eligible</td>
<td>22%</td>
</tr>
</tbody>
</table>

A total 127 (22%) of the projects passed the application process, of which 41% had industry partners, 34% had partnerships with other foundations, 25% had partnerships with Dutch foundations with ANBI status (Table 7). The PPP (TKI) Program application for 2017 resulted in a total amount of € 12.7 million available for funding new projects through the PPP Project Allowance.
Table 7: TKI-Program application results (2015 - 2017)

Grondslag

<table>
<thead>
<tr>
<th>Year</th>
<th>Nr of Projects applied</th>
<th>Applied Grondslag</th>
<th>Toekenning Grondslag</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>32</td>
<td>€ 3.996.808,00</td>
<td>€ 760.620,00</td>
</tr>
<tr>
<td>2017</td>
<td>127</td>
<td>€ 12.705.062,00</td>
<td>€ 2.180.000,00</td>
</tr>
</tbody>
</table>

PPS

<table>
<thead>
<tr>
<th>Nr of Projects applied PPS</th>
<th>Projects toegekend PPS</th>
<th>Toegekende PPS toeslag</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prior to TTO involvement</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>3 *</td>
<td>€ 1.063.704,00</td>
</tr>
</tbody>
</table>

* 5 projects pending for april 2018 for €1.641.268

It is evident that TTO’s PPP (TKI) Program application for 2017, with approximately € 12.7 million, resulted in a higher allocated PPP (TKI) Program allowance than that of previous years.

PPP-Allowance

Apart from evaluating projects for the PPP (TKI) Program, TTO along with RDO, also took the responsibility for identifying individual projects for the PPP Project Allowance, a funding opportunity also aimed at research and development collaborations between Erasmus MC and private partners.

TTO acts as an intermediary between all PPP Project Allowance applicants and Health Holland to ensure that both the researchers, and thus Erasmus MC, benefits from the generated PPP (TKI) Program allowance. The duties of acting as intermediary not only includes vetting potential projects for the PPP Project Allowance, but also supporting the project’s application with the aid of the Erasmus MC’s PPP Project Allowance.

In 2017, Erasmus MC applied with three projects for € 1,063,704.00 PPP Project Allowance, which were granted in December 2017.
Outlook 2018

Business Development

For 2018, we expect the number of IDs, IDFs signed and Patent Applications to remain more or less at the same level or even to increase slightly. The number of licenses and spin-offs should increase further, based on the maturity status of IDs from 2015 and 2016.

The development of the royalty income for 2018 is difficult to predict. It is however, expected that the royalty income will begin to increase again in either 2018 or 2019.

In 2018, we will also make some small changes in the setup of our services, as we see that—as a natural consequence of finalising more license deals—we may need more expertise and attention for the support of spin-offs. Together with the expected EFROII subsidy (working title “ErasSupport”), we will be able to provide much better support to inventions that may develop into a spin-off.

Legal

We expect to have reached a saturation level for the development of the Legal activities of TTO. With the new software tool we expect to be able to manage the workflow better and be able to better adapt to peaks in the workflow.

Financial

Since we have reached the saturation level of a well-established TTO, we can start to look for stabilising the financial structure. TTO as a service department needs a stable financial structure. It is impossible to manage a service department based on project-financing in the long term. Therefore, in 2018 we will start to make an in-depth assessment of the needs and the possibilities to change the financing structure of TTO.

Incubator and LS&H Hub

In 2018, the public interest for the Incubator may grow, not only because of the success of the Life Science & Health Hub, but also because we may need to plan for a second floor for lab and office space. A second LS&H floor will be developed for the LS&H Hub due to its enormous success. Together with the Municipality of Rotterdam and other stakeholders in the Rotterdam Science Tower, this will be a project with major impact for the Life Science & Health sector in Rotterdam.

The move of the European Medicines Agency to Amsterdam may also have an impact on these developments.

Holding

The success of the BD team may result in the growth of the number of participations of Erasmus MC. All these participations will be managed by the Holding and we expect the list of participations to grow in 2018.
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