CONNECT BIOBANKS,
INCREASE VISIBILITY,
MAKE NEW TREATMENTS POSSIBLE.

ANNUAL REPORT
2018
Biobanks (and Biomolecular Resources Centres)’ means collections, repositories and distribution centres of all types of human biological samples, such as blood, tissues, cells or DNA and/or related data such as associated clinical and research data, as well as biomolecular resources, including model- and micro-organisms that might contribute to the understanding of the physiology and diseases of humans.

BBMRI-ERIC Statutes, Article 1(1)
CONNECT BIOBANKS, INCREASE VISIBILITY, MAKE NEW TREATMENTS POSSIBLE.
Dear delegates of the Assembly, dear National Node Directors, dear Sir/Madam,

I am pleased to report that 2018 was a strong year for BBMRI-ERIC: we saw the first results of the new vision to further build and strengthen value-added sustainable biobanking for all stakeholders. We are proud to say that our central office in Graz, as well as our 20 Member States and 1 international organization, truly delivered on their commitments and enabled academia and industry to make new treatments possible.

For the National Nodes and their biobanks, the road towards a more service-oriented approach has been paved. The representatives of patient organizations are fully up to speed within the Stakeholder Forum, where more than 10 new organizations joined since 2017. For clinicians and policymakers the awareness and understanding of the capabilities of the largest health infrastructure is increasing – preparing us for a strong future. Here are some highlights of the main accomplishments from 2018 that contributed to our stakeholders and improved our efforts, using our Work Programme 2018 as framework.

A start was made by measuring the performance and impact of certain activities with monthly key performance indicators. In this annual report several will be highlighted, where the strong growth in quality-related services and the achievements in communications stand out!

STRATEGY AND PARTNERSHIPS

Together we published our Vision Paper in 2018, which will guide us in the years ahead. Going forward we strongly believe that BBMRI-ERIC will be part of a total workflow for health research and personalised medicine, where biobanks are the key drivers in enabling academia and industry to make new treatments possible. Our new strategy is fully in line with our mission: to establish, operate and develop a pan-European, distributed research infrastructure of biobanks and biomolecular resources to facilitate access to resources and facilities in order to support high-quality biomedical research.

The contributions in expertise and know-how from our Member States remain the cornerstone on which this infrastructure is built. That is why I was excited when, in May 2018, the Bulgarian Ministry of Education and Science showed confidence in BBMRI-ERIC and its network and sent a successful application to become our 21st member, making BBMRI the biomedical ERIC with the largest membership in Europe.

A key element of the Vision Paper and Work Programme 2018 is the need for collaboration. We invested time and resources expanding the network of formal and informal partnerships. BBMRI-ERIC, EATRIS and ECRIN released a joint statement on Horizon Europe in September. Speaking at ICRI 2018, the International Conference for Research Infrastructures in Vienna, I had the chance to meet Commissioner Carlos Moedas and present him with a hard copy of the statement. Participation in roundtable discussions on the planned Mission on Cancer, “Boosting the social impact of innovative cancer research” during the Gago Conference in Porto and the Vatican as well as our involvement in the European Cancer Moonshot, driven by the University of Lund in Sweden, are good examples of how BBMRI-ERIC and the biobank community can truly make an impact on the bigger picture. Next to these larger events BBMRI-ERIC is structurally represented in Brussels via regular meetings with relevant policy makers such as the European Commission DG RTD.
Through ADOPT BBMRI-ERIC, our flagship project, art and biobanking came together in a year-long collaboration between BBMRI-ERIC and the Art & Science faculty at the University of Applied Arts Vienna in Austria. Through a series of workshops and guided visits to biobanks, a foundation was laid for students to produce and exhibit artistic works related to biobanking. A final exhibition of artistic works by Art & Science students in May-June 2019 creates a new space for fresh ideas and perspectives with regards to biobanking activities, thereby engaging and educating not only the existing biobanking community, but also new audiences in novel and imaginative ways.

INCREASING VISIBILITY AND AWARENESS

To effectively link those that have collected millions of samples and associated data and those that are looking for samples to drive their research, it is crucial to be aware of the needs and services that can be delivered. The creation of a new corporate identity for BBMRI-ERIC was an important milestone for increasing our marketing and communication efforts. The revamp of the website, including search engine optimization, continuous communication via social media (LinkedIn and Twitter), a new exhibition booth and redesigned printed materials are some examples of the achievements by the team.

One highlight was a visit in December from EURONEWS to film a segment on ADOPT and the Colorectal Cancer Cohort, the National Nodes and the biobanks; the 4-minute news segment had a potential reach of 400 million homes in 160 countries: https://www.euronews.com/2019/01/14/european-research-ers-tackle-cancer-with-biobanks
Communicating to our stakeholders about our plans, achievements and opinions also requires a thorough understanding of the trends and issues in the world around us. The creation of a monitoring system for news and events with the Policy Task Force and Stakeholder Forum is in place and in 2019 will be made available for all National Nodes.

EUROPE BIOBANK WEEK IN ANTWERP

Hosted by BBMRI-ERIC and ESBB, the 2018 edition of Europe Biobank Week took place in Antwerp from September 4th to 7th. The pre-conference day kicked off with workshops on a variety of topics from the use of social media to professionalising biobanking as a career, followed by ESBB working group meetings in the afternoon. The conference officially opened its doors on Wednesday, welcoming more than 600 participants to the spectacular venue next to the Antwerp zoo. Thought-provoking, witty and controversial at times, the keynote address by Peter Hinssen was a highlight of the week. The rest of the programme covered popular topics such as quality management, the impact of the GDPR on biobanking, stakeholder engagement, data sharing, IT tools, and big data, to name a few. I am especially pleased that several National Nodes opted for a booth this year, showcasing their most important activities and achievements.

SERVICES

The transition of BBMRI-ERIC to a reliable service provider for biomedical researchers in Europe kicked off with a review of our core services - Quality, IT and ELSI - to bring them to a mature stage. We asked ourselves: “How can BBMRI best help the National Nodes and their biobanks to further increase the access to high-quality samples and associated data?”

First, the Common Service IT developed the Directory, our sample catalogue with over 100 million samples from 578 biobanks, and the Negotiator to facilitate and support access for the various end users. New versions were released, and feedback from the National Nodes was incorporated to optimize the user experience, resulting in almost doubling the number of biobanks connected to the Negotiator. In addition, Common Service IT played a crucial role in the Colorectal Cancer Cohort (CRC-Cohort) as part of the EU-funded project ADOPT BBMRI-ERIC (H2020), which serves as another excellent use case in making European biobanks visible and improving access to their collections of samples. One goal of the project was to gather 10,000 existing colon cancer datasets from either formalin-fixed paraffin embedded (FFPE) or fresh frozen tissue samples of surgical material. In combination with detailed anonymized pathological and clinical data associated with the samples a unique resource will be available for future research, in line with one of the goals of BBMRI-ERIC: making new treatments possible.

Second, our Quality Management services are designed to guide biobanks and laboratories step by step towards excellence via three pillars: the knowledge hub, training & support, and auditing. Strong results were achieved with 88 completed Self-Assessment Surveys, the addition of 15 collections with a Q-mark to the Directory and a series of 14 webinars with an average of approximately 50 participants each. Being recognized not only within the Member States, but also in projects on this topic such as ConcePTION (IMI call on breastmilk) and SPIDIA4P is a clear indication that we are on the right track and can lead the global discussion on quality of samples and biobanking.
Third, the organizational structure, mission, orientation and achievements of the Common Service ELSI had been reviewed during 2018, in order to assess how better to deliver its required services. Recommendations were given in relation to the setup of the governance structure and how to maximize efficiency by strategic planning and priority setting, especially for current and future projects. Also, the tasks as well as the allocation of resources within the Common Service ELSI, its Task Forces and the role of the national ELSI node experts needed to be clearer and supported by a specific mandate.

The Common Service ELSI centred its efforts around a number of services and support, including optimising the ELSI Helpdesk and Knowledge Base, adapting the Ethics Check and responding to public consultations such as the WP29 guidelines on consent. An internal operating procedure for the handling of the ELSI Helpdesk enquiries was drafted and refined to streamline processes. Furthermore, the ELSI Helpdesk Review Board was formed as a port of call to discuss and review incoming questions. In parallel, the ELSI Knowledge Base began to be populated with practical information concerning key ELSI topics relevant in biobanking, in the form of both documentation and educational videos.

**CODE OF CONDUCT**

The EU General Data Protection Regulation entered into force on 25 May 2018, with direct effect in Member States. Given that legal texts are not always easily accessible, BBMRI-ERIC is leading an initiative around a Code of Conduct for Health Research that is as comprehensive as possible to guide researchers and administrative staff, reduce unnecessary fear relating to compliance and enhance data sharing for stimulating progress in research. BBMRI-ERIC was active at the Computers, Privacy and Data Protection (CPDP) Conference in Brussels, 24-26 January 2018, by organising the panel session, “Code of Conduct for Health Research: A Resource in Turbulent Times?”. Experts and stakeholders were brought together during a panel session to introduce and discuss the Code, which was born from the collaboration of more than 90 research organisations.

During 2018 several drafting group meetings took place face to face and via phone to work on a draft. Public consultation will be available at the earliest 2019/2020; the exact date is pending.

**FINANCE BUDGET AND PROJECTS**

In the goal tree of 2018 was a clear statement concerning finance: BBMRI-ERIC needs to meet or exceed our financial commitments. With a core budget of approximately €2.57 million approved by the Assembly of Members we were jointly able to deliver on the actions described in the Work Programme and deviated only 1.6% from the approved budget (a difference mainly caused by two Member States that haven’t been able to fulfil their financial obligations).

Finally, strategic efforts concerning funding were intensified in 2018 and I am happy to share that this approach has paid off. By actively monitoring market developments, we detected upcoming calls at an early stage and searched for collaboration with other RIs and consortia. In the second half of 2018, we were awarded an unprecedented 8 EU-funded projects out of 12 submissions, including EOSC-LIFE, EJP RD, euCanSHare and EUCAN-Connect, where BBMRI-ERIC and National Nodes are partners, in the ERIC Forum we are acting as coordinator. Further in the report, a table provides an overview of all the successful applications that can support our and our partners’ research, which in total represents an amount of €3.3 million for the coming 5 years. One result of this effective approach is that significant pre-financing per project was received from the European Commission towards the end of the year,
significantly increasing the cash position of BBMRI-ERIC and the assets on the balance sheet compared to 2017.

The financials of BBMRI-ERIC reflect our achievement throughout the past 5 years since coming into existence, signalling our "coming of age" to become a stable and mature European research infrastructure.

As this progress clearly shows, BBMRI-ERIC is entering a new stage of maturity. Our success with EU projects demonstrates more than ever that we are a trusted project partner, while the success of ADOPT BBMRI-ERIC has proven the feasibility of our mission of pan-European cooperation to enhance clinical research. We are extremely grateful to our hardworking National Nodes and project partners for their contributions to the success of BBMRI-ERIC, and we look to the years ahead with great optimism.

Together, we can empower biobanks to drive prevention and enable academia and industry to make new treatments possible.

Sincerely,

Erik Steinfelder, Director General
May 2019
Services

DIRECTORY

578 biobanks connected
>100 million samples
17 countries contributing collections
443 average users per month

NEGOTIATOR

94 biobanks connected
145 average users per month

QM

88 Self-Assessment completions
15 additional collections with Q-Mark

ELSI

94.3% successful response rate for helpdesk questions
11 Ethics checks for H2020 EU projects
PART 2
FINANCIAL INFORMATION
CONNECT BIOBANKS,
INCREASE VISIBILITY,
MAKE NEW TREATMENTS POSSIBLE.
## Profit & Loss Statement

<table>
<thead>
<tr>
<th>In EUR</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turnover</td>
<td>3,631,636</td>
<td>888,860</td>
<td>2,892,951</td>
<td>3,050,231</td>
</tr>
<tr>
<td>Other operating income</td>
<td>62,137</td>
<td>-</td>
<td>629</td>
<td>1,068</td>
</tr>
<tr>
<td>Material Expenses</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Staff expenses</td>
<td>(887,215)</td>
<td>(1,554,036)</td>
<td>(1,689,010)</td>
<td>(1,647,023)</td>
</tr>
<tr>
<td>Amortization</td>
<td>(30,454)</td>
<td>(30,020)</td>
<td>(29,518)</td>
<td>(35,896)</td>
</tr>
<tr>
<td>Other operating expenses</td>
<td>(687,764)</td>
<td>(1,172,010)</td>
<td>(1,367,820)</td>
<td>(1,464,964)</td>
</tr>
<tr>
<td><strong>Operating result</strong></td>
<td><strong>2,088,340</strong></td>
<td><strong>(1,867,207)</strong></td>
<td><strong>(192,768)</strong></td>
<td><strong>(96,584)</strong></td>
</tr>
<tr>
<td>Other interest and similar income</td>
<td>16</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Interest and similar expenses</td>
<td>-</td>
<td>(58)</td>
<td>(30)</td>
<td>(41)</td>
</tr>
<tr>
<td>Financial result</td>
<td>16</td>
<td>(58)</td>
<td>(30)</td>
<td>(41)</td>
</tr>
<tr>
<td><strong>Loss from operating activities, Earnings before taxes</strong></td>
<td><strong>2,088,356</strong></td>
<td><strong>(1,867,265)</strong></td>
<td><strong>(192,798)</strong></td>
<td><strong>(96,626)</strong></td>
</tr>
<tr>
<td>Taxes on income and revenue</td>
<td>(4)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Profit of the year</strong></td>
<td><strong>2,088,352</strong></td>
<td><strong>(1,867,265)</strong></td>
<td><strong>(192,798)</strong></td>
<td><strong>(96,626)</strong></td>
</tr>
<tr>
<td>Reversal of profit reserves</td>
<td>-</td>
<td>1,867,265</td>
<td>192,798</td>
<td>96,626</td>
</tr>
<tr>
<td>Allocation to profit reserves</td>
<td>(2,034,352)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Profit carried forward from the previous years</strong></td>
<td><strong>313,775</strong></td>
<td><strong>367,775</strong></td>
<td><strong>367,775</strong></td>
<td><strong>367,775</strong></td>
</tr>
<tr>
<td><strong>Balance sheet profit</strong></td>
<td><strong>367,775</strong></td>
<td><strong>367,775</strong></td>
<td><strong>367,775</strong></td>
<td><strong>367,775</strong></td>
</tr>
</tbody>
</table>
Key Facts & Figures

17 member states

92% projects on track

2.5 m overall budget

4 observers

SOCIAL MEDIA

650 new followers

278 new followers

> 650,000 impressions
## Balance Sheet

<table>
<thead>
<tr>
<th></th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intangible Assets</td>
<td>3,840</td>
<td>2,560</td>
<td>1,280</td>
<td>8,459</td>
</tr>
<tr>
<td>Tangible Assets</td>
<td>112,120</td>
<td>87,759</td>
<td>73,274</td>
<td>55,924</td>
</tr>
<tr>
<td><strong>Fixed Assets</strong></td>
<td><strong>115,960</strong></td>
<td><strong>90,320</strong></td>
<td><strong>74,554</strong></td>
<td><strong>64,382</strong></td>
</tr>
<tr>
<td>Receivables and other Assets</td>
<td>93,179</td>
<td>145,488</td>
<td>199,669</td>
<td>1,164,191</td>
</tr>
<tr>
<td>Receivables arising from deliveries services</td>
<td>130</td>
<td>9,249</td>
<td>126,626</td>
<td>134,301</td>
</tr>
<tr>
<td>Other receivables and assets</td>
<td>93,049</td>
<td>136,239</td>
<td>73,043</td>
<td>1,029,890</td>
</tr>
<tr>
<td>Cash on hand and Bank deposits</td>
<td>3,625,026</td>
<td>1,970,135</td>
<td>2,189,624</td>
<td>1,645,101</td>
</tr>
<tr>
<td><strong>Current Assets</strong></td>
<td><strong>3,718,204</strong></td>
<td><strong>2,115,623</strong></td>
<td><strong>2,389,293</strong></td>
<td><strong>2,809,292</strong></td>
</tr>
<tr>
<td>Prepaid expenses, deferred charges</td>
<td>250</td>
<td>3,581</td>
<td>5,919</td>
<td>13,332</td>
</tr>
<tr>
<td><strong>Assets</strong></td>
<td><strong>3,834,415</strong></td>
<td><strong>2,209,523</strong></td>
<td><strong>2,469,766</strong></td>
<td><strong>2,887,006</strong></td>
</tr>
<tr>
<td>Reserves pursuant to the articles of association</td>
<td>2,193,362</td>
<td>326,097</td>
<td>133,300</td>
<td>36,674</td>
</tr>
<tr>
<td>Balance sheet profit</td>
<td>367,775</td>
<td>367,775</td>
<td>367,775</td>
<td>367,775</td>
</tr>
<tr>
<td><strong>Capital and Reserves</strong></td>
<td><strong>2,561,137</strong></td>
<td><strong>693,872</strong></td>
<td><strong>501,075</strong></td>
<td><strong>404,449</strong></td>
</tr>
<tr>
<td>Other accruals</td>
<td>24,669</td>
<td>52,800</td>
<td>128,178</td>
<td>832,308</td>
</tr>
<tr>
<td><strong>Accruals</strong></td>
<td><strong>24,669</strong></td>
<td><strong>52,800</strong></td>
<td><strong>128,178</strong></td>
<td><strong>832,308</strong></td>
</tr>
<tr>
<td>Liabilities arising from deliveries and services</td>
<td>31,407</td>
<td>54,179</td>
<td>58,187</td>
<td>164,723</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>24,823</td>
<td>204,924</td>
<td>157,418</td>
<td>131,022</td>
</tr>
<tr>
<td><strong>Liabilities</strong></td>
<td><strong>56,230</strong></td>
<td><strong>259,104</strong></td>
<td><strong>215,604</strong></td>
<td><strong>295,745</strong></td>
</tr>
<tr>
<td>Deferred income</td>
<td>1,192,378</td>
<td>1,203,748</td>
<td>1,624,910</td>
<td>1,354,505</td>
</tr>
<tr>
<td><strong>Liabilities and Owner´s Equity</strong></td>
<td><strong>3,834,415</strong></td>
<td><strong>2,209,523</strong></td>
<td><strong>2,469,766</strong></td>
<td><strong>2,887,006</strong></td>
</tr>
</tbody>
</table>
## Cash Flow

<table>
<thead>
<tr>
<th>In EUR</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profit of the year</td>
<td>(1.867.265)</td>
<td>(192.798)</td>
<td>(96.626)</td>
</tr>
<tr>
<td>Amortization</td>
<td>29.955</td>
<td>28.096</td>
<td>31.878</td>
</tr>
<tr>
<td><strong>Cash Flow from the Result</strong></td>
<td>(1.837.309)</td>
<td>(164.702)</td>
<td>(64.748)</td>
</tr>
<tr>
<td>Receivables arising from deliveries services</td>
<td>(9.119)</td>
<td>(117.377)</td>
<td>(7.675)</td>
</tr>
<tr>
<td>Other receivables and assets</td>
<td>(43.190)</td>
<td>63.196</td>
<td>(956.847)</td>
</tr>
<tr>
<td>Liabilities arising from deliveries and services</td>
<td>22.772</td>
<td>4.007</td>
<td>106.536</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>180.102</td>
<td>(47.507)</td>
<td>(26.396)</td>
</tr>
<tr>
<td>Prepaid expenses, deferred charges</td>
<td>(3.331)</td>
<td>(2.337)</td>
<td>(7.414)</td>
</tr>
<tr>
<td>Accruals</td>
<td>39.500</td>
<td>496.540</td>
<td>433.725</td>
</tr>
<tr>
<td><strong>Working Capital</strong></td>
<td>186.733</td>
<td>396.523</td>
<td>(458.070)</td>
</tr>
<tr>
<td><strong>Cash Flow from Operations</strong></td>
<td>(1.650.576)</td>
<td>231.820</td>
<td>(522.817)</td>
</tr>
<tr>
<td><strong>Cash Flow from Investing Activities</strong></td>
<td>(4.315)</td>
<td>(12.331)</td>
<td>(21.706)</td>
</tr>
<tr>
<td><strong>Capital and Reserves</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cash Flow from Financing Activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Cash Flow</strong></td>
<td>(1.654.891)</td>
<td>219.490</td>
<td>(544.523)</td>
</tr>
<tr>
<td>Cash Beginning</td>
<td>3.625.026</td>
<td>1.970.135</td>
<td>2.189.624</td>
</tr>
<tr>
<td>Δ</td>
<td>(1.654.891)</td>
<td>219.490</td>
<td>(544.523)</td>
</tr>
<tr>
<td>Cash End</td>
<td>3.625.026</td>
<td>1.970.135</td>
<td>2.189.624</td>
</tr>
</tbody>
</table>
Notes on the Financial Statements for the Financial Year 2018

A) ACCOUNTING AND VALUATION PRINCIPLES

1. GENERAL PRINCIPLES

The financial statements as of December 31, 2018 were prepared in accordance with current accounting principles of the Austrian Commercial Code (UGB). The Financial Statements were prepared under the Generally Accepted Accounting Principles, giving a true and fair view of the Association’s financial position.

The principle of completeness was applied at preparation of the Financial Statements.

The evaluation of assets and liabilities was carried out considering the principle of individual items valuation and the going concern concept. The principle of prudence was considered by showing only the realized gains at balance sheet date. All recognizable risks and possible future losses arisen in the fiscal year were taken into account.

2. ASSETS

Intangible assets
Intangible assets are valued at acquisition cost reduced by straight-line depreciation. Scheduled depreciation is based on the following useful lives:

<table>
<thead>
<tr>
<th>Intangible assets</th>
<th>Useful life in years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software</td>
<td>4 – 5</td>
</tr>
</tbody>
</table>

Fixed assets
Fixed assets are valued at acquisition or manufacturing cost reduced by straight-line depreciation. Low value assets (acquisition value up to EUR 400.00) are fully depreciated in the year of acquisition. Scheduled depreciation is based on the following useful lives:

<table>
<thead>
<tr>
<th>Fixed assets</th>
<th>Useful life in years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixtures and fittings</td>
<td>1 – 15</td>
</tr>
</tbody>
</table>

3. ACCOUNTS RECEIVABLE AND OTHER ASSETS

Accounts receivable are valued at their nominal value. Recognizable risks are considered by individual allowances.

4. PROVISIONS

Provisions are calculated according to legal requirements and considering all recognizable risks and anticipated losses. All provisions have a term of less than one year.

5. LIABILITIES

Liabilities are valued at repayment amounts.

6. FOREIGN CURRENCY TRANSLATIONS

Foreign currency receivables are converted using the exchange rate at the date of initial recognition or at balance sheet date if lower. Foreign currency liabilities are converted using the exchange rate of initial recognition or at balance sheet date if higher.
B) NOTES TO THE BALANCE SHEET AND THE PROFIT AND LOSS ACCOUNT

1. NOTES TO THE BALANCE SHEET

Fixed assets
The development of fixed assets and details to the depreciation are shown in the attached schedule (Appendix).

Revenues, payable after the balance sheet date
Other receivables include the following significant revenues, payable after the balance sheet date.

<table>
<thead>
<tr>
<th></th>
<th>2018-12-31</th>
<th>2017-12-31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project revenues</td>
<td>968,487.56</td>
<td>0.00</td>
</tr>
<tr>
<td>Other receivables</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Provisions
Other provisions have developed as follows:

<table>
<thead>
<tr>
<th></th>
<th>Status 2018-01-01</th>
<th>Usage</th>
<th>Allocation</th>
<th>Status 2018-12-31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other provisions</td>
<td>EUR</td>
<td>EUR</td>
<td>EUR</td>
<td>EUR</td>
</tr>
<tr>
<td>Other provisions</td>
<td>49,805.63</td>
<td>40,727.28</td>
<td>772,210.08</td>
<td>781,288.43</td>
</tr>
<tr>
<td>Provisions for salary payment</td>
<td>21,000.00</td>
<td>21,000.00</td>
<td>8,026.16</td>
<td>8,026.16</td>
</tr>
<tr>
<td>Provisions for annual leave</td>
<td>41,872.10</td>
<td>41,872.10</td>
<td>27,492.96</td>
<td>27,492.96</td>
</tr>
<tr>
<td>Provision for consulting expenses</td>
<td>15,500.00</td>
<td>15,500.00</td>
<td>15,500.00</td>
<td>15,500.00</td>
</tr>
<tr>
<td></td>
<td>128,177.73</td>
<td>119,099.38</td>
<td>823,229.20</td>
<td>832,307.55</td>
</tr>
</tbody>
</table>

Expenses, payable after the balance sheet date
Other liabilities include the following significant expenses, payable after the balance sheet date.

<table>
<thead>
<tr>
<th></th>
<th>2018-12-31</th>
<th>2017-12-31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff expenses</td>
<td>82,359.39</td>
<td>95,370.69</td>
</tr>
<tr>
<td>Other operating expenses</td>
<td>48,354.76</td>
<td>59,864.95</td>
</tr>
<tr>
<td></td>
<td>130,714.15</td>
<td>155,235.64</td>
</tr>
</tbody>
</table>

Deferred income statement items
BBMRI-ERIC receives grant payments from the public sector for the coordination and execution of projects. The disbursements of these grant payments are partly carried out at the beginning of the project phases. The grant payments are allocated to the actual expenses incurred and are distributed over deferred income. As in the previous year, deferred income contains these deferred grant payments.
Liabilities due the use of fixed assets not recognized on the balance sheet

<table>
<thead>
<tr>
<th>Other provisions</th>
<th>following year</th>
<th>following 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liabilities from leasing contracts</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Liabilities from rental contracts</td>
<td>103,809.96</td>
<td>519,049.80</td>
</tr>
<tr>
<td>other Liabilities</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td></td>
<td>103,809.96</td>
<td>519,049.80</td>
</tr>
</tbody>
</table>

2. NOTES TO THE PROFIT- AND LOSS ACCOUNT

The profit and loss statement is presented in the total cost format.

Breakdown of revenues
According to § 240 UGB, a breakdown of the revenues is not possible, since this would be a reasonable disadvantage for BBMRI-ERIC.

3. EXPENSES FOR THE AUDITOR

The expenses for the auditor for the financial year amount to EUR 6,500 (previous year: EUR 6,500) and relate exclusively to audit services.
CONNECT BIOBANKS,
INCREASE VISIBILITY,
MAKE NEW TREATMENTS POSSIBLE.
Projects Awarded in 2018

We are thrilled to announce that we were successfully awarded funding for 8 additional projects by the European Commission in 2018.

<table>
<thead>
<tr>
<th>CINECA</th>
<th>ConcePTION</th>
<th>EJP RD</th>
<th>EOSC-Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>BBMRI-ERIC Budget</td>
<td>BBMRI-ERIC Budget</td>
<td>BBMRI-ERIC Budget</td>
<td>BBMRI-ERIC Budget</td>
</tr>
<tr>
<td>€ 314,682.50</td>
<td>€ 196,000.00</td>
<td>€ 742,815.50</td>
<td>€ 1,144,288.75</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Start Date</th>
<th>Start Date</th>
<th>Start Date</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019 JANUARY</td>
<td>2019 APRIL</td>
<td>2019 JANUARY</td>
<td>2019 MARCH</td>
</tr>
</tbody>
</table>

International flagship collaboration with Canada for human data storage, integration and sharing to enable personalised medicine approaches.

Building an ecosystem for better monitoring and communicating of medication safety in pregnancy and breastfeeding: validated and regulatory endorsed workflows for fast, optimised evidence generation.

European Joint Programme on Rare Diseases creates a comprehensive, sustainable ecosystem allowing a virtuous circle between research, care and medical innovation.

Providing an open collaborative space for digital biology in Europe.

<table>
<thead>
<tr>
<th>ERIC Forum</th>
<th>EUCAN-Connect</th>
<th>euCanSHARE</th>
<th>RI-VIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>BBMRI-ERIC Budget</td>
<td>BBMRI-ERIC Budget</td>
<td>BBMRI-ERIC Budget</td>
<td>BBMRI-ERIC Budget</td>
</tr>
<tr>
<td>€ 181,250.00</td>
<td>€ 399,326.25</td>
<td>€ 104,675.00</td>
<td>€ 248,500.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Start Date</th>
<th>Start Date</th>
<th>Start Date</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019 JANUARY</td>
<td>2019 JANUARY</td>
<td>2018 DECEMBER</td>
<td>2019 FEBRUARY</td>
</tr>
</tbody>
</table>

Policy and international cooperation measures for research infrastructures.

A federated FAIR platform enabling large-scale analysis of high-value cohort data connecting Europe and Canada in personalized health.

An EU-Canada joint infrastructure for next-generation multi-Study Heart research.

Expanding research infrastructure visibility to strengthen strategic partnerships.

In addition, we continued and completed several other projects in 2018, including our project ADOPT BBMRI-ERIC, which concluded in March 2019.
Our National and Organizational Nodes are the powerhouses behind the work we do. They coordinate the biobanks within their countries while actively contributing to research and growing our sample collections. Here is a snapshot of what makes each Node unique, and we encourage readers to see additional information on each Node’s individual website.
CONNECT BIOBANKS,
INCREASE VISIBILITY,
MAKE NEW TREATMENTS POSSIBLE.
KEY SUCCESSES

• Harmonization & standardization: Internal quality management (QM) cross audit series completed; expertise input to quality standard development at ISO and CEN, 3/4 BBMRI.at biobanks and first Vet Biobank with quality marked collections in BBMRI-ERIC Directory; BBMRI-ERIC Self-Assessment Tool updated/maintained; education provided (e.g. first graduates from MSc Biobanking at MUG).

• Data Management: Major provider of data sets to the ADOPT BBMRI-ERIC colon cancer cohort; all 4 biobanks listed in BBMRI at Catalogue & BBMRI-ERIC Directory and sample quality marks displayed; all biobanks having representatives registered to the Negotiator, best abstract award for BiBBoX abstract at ESDIP; establishment of a high capacity digitalization process for digital pathology slides; BBMRI-ERIC tools promoted on conferences, website, in courses, and publications (e.g. Self-Assessment Survey Tool, BBMRI Directory, BiBBoX).

• Stakeholder and user information and engagement: Workshops with citizens/patients; Translational Science Forum with industry representatives; university biobanking workshops for children’s performed and honoured with PR award; presentations at several conferences; participation in Austria-wide Long Night of Research with workshops and guided biobank tours. Information of users/stakeholders about BBMRI-ERIC tools by promoting them on conferences, website, in courses, and publications (e.g. Self-Assessment Survey Tool, BBMRI Directory, BiBBoX).
BBMRI.be

BELGIUM

AREAS OF EXPERTISE

13 / 19
Number of biobanks and stand-alone collections

1,500,000
Number of samples / size of collections

1.25 FTE/yr; 4 headcount
Number of staff

• Clinical biobanks
• Disease-oriented biobanks
• Quality management of samples and data

KEY SUCCESSES

• Implementation of the Belgian Biobank Law and publication of a compendium with FAQs to help the local biobanks with the implementation of this law: https://www.bbmri.be/wp-content/uploads/2018/08/compendium_20072018_0.pdf

• Publication of the results of the Multistakeholder dialogue in prioritizing hepatology research and biobanking project: https://en.calameo.com/read/001774295e133541a211d?authid=phjYPGbx0WO3D

• Setup of the new governance structure of BBMRI.be allowing our biobank network to expand: https://www.bbmri.be/interested-to-join-bbmri-be/
BBMRI.bg

BULGARIA

AREAS OF EXPERTISE

- Oncology
- Rare diseases
- Neuropsychiatry

| Number of biobanks and stand-alone collections | 1 |
| Number of samples / size of collections | 20,000 |
| Number of staff | 1 |

KEY SUCCESSES

- Bulgaria joined BBMRI-ERIC as full member on 23 May 2018
- Biobanking and BBMRI-ERIC were presented to the public during the European Researchers’ Night 2018
- Medical University of Sofia presented the research infrastructure for biomedical and translational research, including the Biobanking Core Facility to the broad scientific community and National Science Fund, Ministry of Education and Science
BBMRI.cy

CYPRUS

AREAS OF EXPERTISE

1 / 4
Number of biobanks and stand-alone collections

5,000*
Number of samples / size of collections

2
Number of staff

KEY SUCCESSES

• Attraction of funding for more genetics studies and a clinical trial for an inherited renal disease
• Success in H2020/TEAMING program with Advanced Partners being BBMRI-ERIC and Medical University Graz
• Leading a European Consortium in search of genetic modifiers in Alport syndrome

ADDITIONAL COMMENTS

There are also other smaller collections in Cyprus that we have no information about, as there is no Cyprus-wide biobanking under one node, yet. Our Biobank is the first and approved to operate as such, by the Cyprus National Bioethics Committee.

* About 5,000 DNA samples, 25–35% of which are also accompanied by plasma, serum, urine
KEY SUCCESSES


- University hospitals FNB, FNuSA to set up a collaboration with EURACAN European network for rare cancers (http://euracan.ern-net.eu/cs/domu).

- BBMRI-CZ biobanks are actively involved in the design and development of IT tools BBMRI-ERIC Directory and BBMRI-ERIC Negotiator. We participated in developing them in collaboration with the Institute of Computer Science and BBMRI-ERIC’s CS IT. In November 2018 the BBMRI-ERIC Connector was launched at MMC1 for pilot testing. FM HK CU performed a study to assess different preanalytical variables (time to specimen fixation, different concentrations of formalin and pH) to influence the recovery and quality of immunohistochemistry, PCR methods and in situ hybridization. The results enabled the optimization of the preanalytical phase of these laboratory methods.
Estonian Genome Center

**ESTONIA**

<table>
<thead>
<tr>
<th>AREA OF EXPERTISE</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biobanking</td>
<td></td>
</tr>
<tr>
<td>Recontacting</td>
<td></td>
</tr>
<tr>
<td>Feedback</td>
<td></td>
</tr>
</tbody>
</table>

**KEY SUCCESSES**

- Recruited 105,000 people into the biobank in 2018 (50,000 will be added in 2019)
- Recontacted over 2,000 people from the biobank, providing them with genetic risk scores based on biobank data
- Key participant in developing personalised medicine activities in Estonia and leading the personalised medicine projects in two largest hospitals in Estonia

**ADDITIONAL COMMENTS**

In 2018 the Estonian Biocentre, an independent research institute outside of University of Tartu, was fused with the Estonian Genome Center of University of Tartu, which resulted in a new research institution: "Institute of Genomics of University of Tartu" (www.biobank.ee).

* By the end of November 2019 we'll have 200,000 people in the biobank and all will be genotyped by early 2020. Today we have 183,000 people in the biobank and 134,000 have been genotyped with GSA array.
KEY SUCCESSES

- Strong national collaboration between biobanks and initiation of the FINBB Biobank cooperative activities aiming to a one-stop-shop for biobank operations
- Collected 100,000 new biobank samples and 120,000 new biobank consents
- Initiated 116 new biobank access projects
KEY SUCCESSES

• Publication of the ISO 20387 standards (Coordination G Dagher)

• Initiation of Self-Assessment Survey in BRCof CEN/TS

ADDITIONAL COMMENTS

In 2018, the NN was in a restructuring period facing departure of FTE and reorientation of the project.
• Launch of donor web portal: In 2018, GBN launched a website with comprehensive information for biomaterial donors: www.biobanken-verstehen.de. Key elements of the website include success stories on research projects that have led to important findings in medical research. The website is part of a donor communication campaign consisting of the website as well as posters and brochures distributed by GBA biobanks and their hosting university hospitals.

• Successful live presentation of the SampleLocator, the federated search across 10 biobanks: At the end of 2018 GBN/GBA gave a first live-presentation of a federated sample search across 10 biobanks. This presentation given to our Scientific Advisory Board evoked great response and we were prompted to “[...] intensive reach out activity – not only in Germany, but also a European level. [...]” Now GBN and GBA are gradually increasing the amounts of biobanks and samples visible in the SampleLocator.

• Qualification of auditors & start of friendly audits: For the realisation of the cross-biobank audits, 15 selected GBA auditors received five days of face-to-face training in June/August 2018. The first friendly audits started according to GBN standard (published open access on Zenodo http://doi.org/10.5281/zenodo.2649142) including ISO 20387 in December 2018.

* 10.8 million tissue; 6 million liquid; 620,000 derivates
KEY SUCCESSES

• Approval of a National Fund (€500,000) to the Central Node and Peripheral Nodes in support of the Greek Biobanking Network

• Upgrading of the Greek Genome Center; the only such Center in Greece and with its equipment can act as an Expert Center for BBMRI-ERIC; see (http://genome.bioacademy.gr/)

• Sample Collection

• Participation in the ELSI Committee of BBMRI-ERIC: The member of the Greek Central Node, Dr. Olga Tzortzatou, a member of the BBMRI-ERIC ELSI team, has participated in the Task Forces of the BBMRI Helpdesk as a data and ethics expert providing consulting for biobanking ELSI issues such as the implementation across EU of GDPR and participating in the initiative of drafting a map regarding Research Ethics Committees landscape across EU.

---

* 4 collections, several others being developed. Specifically, 3 are on diseases/conditions (hematological malignancies, Parkinson’s Disease and pediatric/adolescence obesity) and 1 is a population biobank (part of the EPIC and Hydria collections) with samples from the Greek population

** Over 10,000 (for hematological malignancies); over 1,000 (for Parkinson’s Disease); over 3,000 (for pediatric/adolescent obesity).
BBMRI.it

ITALY

Areas of Expertise

- Healthcare Integrated Biobanking, including imaging biobanks
- ELSI (RECs, Informed consent process, engagement, partnership with patient associations)
- Training (quality, governance, participatory methods and tools)

Number of biobanks and stand-alone collections

95

43% of diseases-oriented biobanks
samples size > 10,000;
samples size of population biobanks > 150,000;
sample size of archived tissue biobanks > 500,000

Number of staff

10 FTE/yr;
18 headcount

KEY SUCCESSES

- Working Groups with RECs, POs, biobankers, researchers, clinicians, industry, ELSI experts (informed consent matrix, ethics review consensus)
- Quality book
- Sustainability and cost recovery
KEY SUCCESSES

- Participation in development of more than 10 national-level and more than 5 international-level research projects, from which 7 national and 2 international projects have been granted funding; research includes areas of diabetes, tumour research, rare disease, ELSI and other.

- Preparation of Biobank law and submission to the National Ministry of Health, currently procedures are ongoing for the final corrections and acceptance

- Biosample digitalization for research, by participation in national large-scale sequencing centre development and participation in research project for next generation sequencing data obtainment

- Organization of national-level activities for biobanks and researchers about ELSI, QM and data protection and local level consultations

* National Biobank: Genome Database of Latvian population: over 35,000;
  Institute of Clinical and Preventive Medicine: over 15,000
BBMRI.mt

MALTA

AREAS OF EXPERTISE

1
Number of biobanks
and stand-alone collections

~ 85,000
Number of samples /
size of collections in 14 collections

3.2
Number of staff

Biobank-led research - Globin, Diabetes, Neuromuscular, Oncology, Population genetics

KEY SUCCESSES

• Contribution of 533 colorectal cancer cases to the ADOPT CRC cohort.

• Organisation of a series of Rare Disease events and workshops to different clinical specialists including paediatricians, neurologists, oncologists and healthcare professionals.

ADDITIONAL COMMENTS

Malta is eager to participate in new research projects similar to ADOPT.
BBMRI.nl

NETHERLANDS

<table>
<thead>
<tr>
<th>Key Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of biobanks and stand-alone collections</td>
<td>200</td>
</tr>
<tr>
<td>Number of samples / size of collections</td>
<td>12,000,000*</td>
</tr>
<tr>
<td>Number of staff</td>
<td>13 FTE/yr; 51 headcount</td>
</tr>
</tbody>
</table>

AREAS OF EXPERTISE

- Population omics/Imaging
- IT for FAIR samples and data
- ELSI

KEY SUCCESSES

- Launch national ELSI Servicedesk
- Dutch Data Prize BBMRI-Omics
- Link Catalogue-Request Portal

* 20 up to 12 million, average 54,000, median 1,000
BBMRI.no

NORWAY

80
Number of biobanks and stand-alone collections

14,300,000
Number of samples / size of collections

12 FTE/yr; 27 headcount
Number of staff

AREAS OF EXPERTISE

• Initiating and running population-based biobanks
• State-of-the-art clinical biobanks for research
• Digitized biobank data - secure solution for handling sensitive big data

KEY SUCCESSES

• Genotyping samples in population-based biobanks
• High-quality, large prospective research biobanks with consensus on SOPs established, and the concept "Multi centre biobanking" piloted and well implemented
• 10 biobanks prepared and ready for industry collaboration
Key Successes

- 2nd Polish Biobanks Conference
- Preparation of Quality Standards for Polish Biobanks and Auditor Manual Handbook Distributed to BBMRI-ERIC for revision and implementation
- Common strategy for the development of IT tools
BBMRI.se

SWEDEN

<table>
<thead>
<tr>
<th>AREAS OF EXPERTISE</th>
</tr>
</thead>
<tbody>
<tr>
<td>• National organization and cooperation</td>
</tr>
<tr>
<td>• Quality</td>
</tr>
<tr>
<td>• Clinical biobanks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>KEY SUCCESSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Recruitment of all key roles across the national infrastructure – including all sample service coordinators and national project managers</td>
</tr>
<tr>
<td>• Successful implementation of projects across the whole national infrastructure, including a dedicated strategy for follow-up and reporting</td>
</tr>
<tr>
<td>• Significant sample access work with the recruitment of 10 sample service coordinators and targeted projects aimed at stimulating sample access throughout the infrastructure</td>
</tr>
</tbody>
</table>

ADDITIONAL COMMENTS

Sweden contributed more than 1,000 cases of colorectal cancer to the ADOPT BBMRI project.

A revamp of certain organizational strategies and priorities will be implemented in accordance with input from Biobank Sweden’s multinational Scientific Advisory Board and insights from 2018.

* 450 biobanks managed by 6 regional biobank centres
Swiss Biobanking Platform

**KEY SUCCESSES**

- Development of a tool to evaluate biobanks
- Standardized biobank regulation for Switzerland
- Data dictionaries for tissue, liquid, veterinary and bacteria biobanks

**SWITZERLAND**

<table>
<thead>
<tr>
<th>10</th>
<th>Number of biobanks and stand-alone collections</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 - 10,000</td>
<td>Number of samples / size of collections</td>
</tr>
<tr>
<td>4.1</td>
<td>Number of staff</td>
</tr>
</tbody>
</table>

**AREAS OF EXPERTISE**

- Governance
- Quality
- Interoperability
**KEY SUCCESSES**

- 5 May 2018: International Workshop on Biobanking for Rare Diseases & Symposium on Bridging Biobanks in MENA Countries to Promote Research and Healthcare (co-funded by the project ADOPT BBMRI-ERIC), Izmir, TR
- Competition of Pilot Phase of Turkish Genome Project (Establishment of Biobank & Generation of WES Data)
- Consultation Meetings with Ethics Review Boards about “Broad consent” and Meetings with Data Privacy Agency about Biobanks
Tissue Directory & Coordination Centre

UNITED KINGDOM

| Number of biobanks and stand-alone collections | 128 |
| Number of samples / size of collections       | 5,007,890 |
| Number of staff                               | 3,5 / 10 |

AREAS OF EXPERTISE

- IT/Data/Discovery
- Stakeholder Engagement

KEY SUCCESSES

- Research programme on researcher needs and preferences in using online sample directories to guide future engagement and refine node services.
- UK Biobanking Showcase Annual Event with 160 delegates working across biobanking in attendance.
- UKCRC Tissue Directory and Coordination Centre/BBMRI.uk embedded within a regional centre of Health Data Research UK to improve linking samples for research with associated clinical data.

ADDITIONAL COMMENTS

As a national node, we have a Directory of resources within the UK which hold samples. For the purposes of this exercise, we have only included the number of biobanks that have completed profiles on the Directory, meaning they have included at least one sample collection or capability to obtain samples prospectively.

We do not have a count of the samples represented on our Directory. We have instead combined the numbers of donors (not samples as a collection may have many samples per donor) at the mid-point range of each collection. This is because we do not ask for collection’s total donor count, but rather an estimation of the number of donors the collection represents.
International Agency for Research on Cancer

Areas of Expertise

1
Number of biobanks and stand-alone collections

6,000,000
Number of samples / size of collections

6 FTE/yr; 8 headcount
Number of staff

Key Successes

- Successful completion of the B3 Africa project
- Release of the Common Minimum Technical Standards for LMIC Biobanking in Cancer (published late in 2017)
- Growth of the BCNet (dedicated global LMIC Biobanking Network) to include 32 institutions from 21 countries
BBMRI-ERIC, Graz

Report on the Audit of the Financial Statements as of December 31, 2018 (Translation)

Notwithstanding any statutory right of third parties to receive or inspect it, this audit report is addressed exclusively to the governing bodies of the Company. The digital copy may not be distributed to third parties unless such distribution is expressly permitted under the terms of engagement agreed between the Company and EY (Ernst & Young Wirtschaftsprüfungsgesellschaft m.b.H.). Considering the requirements of Sec. 274 (7) and (8) Austrian Company Code (UGB), the electronic version does not replace the hardcopy but is an electronic copy thereof.
BBMRI-ERIC, Graz

Report on the Audit of the
Financial Statements
as of December 31, 2018 (Translation)

Duplicate

Ernst & Young
Wirtschaftsprüfungsgesellschaft m.b.H.
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non-binding electronic copy
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Appendix 1 Financial Statements as of December 31, 2017

Appendix 2 General Conditions of Contract for the Public Accounting Professions

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non-binding electronic copy
ANNEX
AUDITOR’S REPORT

BBMRI-ERIC, Graz

December 31, 2018

TRANSLATION

To the Director General
BBMRI-ERIC,
Graz

We have completed the audit of the financial statements as of December 31, 2018 of

Biobanking and BioMolecular resources Research Infrastructure -
European Research Infrastructure Consortium (BBMRI-ERIC), Graz
(referred to as “the Company”),

and report on the result of our audit as follows:

1. AUDIT CONTRACT AND PERFORMANCE OF THE ENGAGEMENT

The Company, represented by the Director General, concluded an audit contract with us to audit the financial statements as of December 31, 2018, including the accounting system pursuant to Sections 269 et seqq. Austrian Company Code UGB.

The Company is a small corporation pursuant to Section 221 Austrian Company Code UGB.

The audit is a voluntary audit.

The audit included assessing whether the statutory requirements were adhered to concerning the preparation of the financial statements.

We conducted our audit in accordance with the legal requirements and generally accepted standards on auditing as applied in Austria. These standards require that we comply with International Standards on Auditing. An auditor conducting an audit obtains reasonable assurance about whether the financial statements are free from material misstatement. Absolute assurance is not attainable due to the inherent limitations of any accounting and internal control system and due to the sample-based test nature of an audit. There is an unavoidable risk that material misstatements in the financial statements remain undetected. Areas which are generally covered in special engagements were not included in our scope of work.

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We performed the audit, with interruptions, in April 2019 mainly at the Company’s premises in Graz. The audit was substantially completed at the date of this report.

Auditor responsible for the proper performance of the engagement is Mr. Erich Lehner, Austrian Certified Public Accountant.

Our audit is based on the audit contract concluded with the Company. The “General Conditions of Contract for the Public Accounting Professions” issued by the Austrian Chamber of Tax Advisers and Auditors (refer to Appendix 2) form an integral part of the audit contract. These conditions of contract do not only apply to the Company and the auditor, but also to third parties. Section 275 Austrian Company Code UGB applies with regard to our responsibility and liability as auditors towards the Company and towards third parties.

2. BREAKDOWN AND DESCRIPTION OF SIGNIFICANT ITEMS IN THE FINANCIAL STATEMENTS

The breakdown and description of all significant financial statement items are included in the notes to the financial statements. Therefore, we refer to the respective disclosures made by the Director General in the notes to the financial statements.
3. SUMMARY OF AUDIT FINDINGS

3.1. Compliance of the accounting system and the financial statements

During our audit, we obtained evidence that the statutory requirements and generally accepted accounting principles in Austria have been complied with.

In line with our risk and controls based audit approach and to the extent we considered necessary for the purpose of expressing an opinion, we considered internal controls related to sub processes of the financial reporting process as part of our audit.

With regard to the compliance of the financial statements with all applicable statutory requirements we refer to the auditor's report.

3.2. Information provided

The Director General and the respective operative employees of BBMRI-ERIC provided all evidence and explanations requested by us. We obtained a representation letter signed by the Director General which we included in our working papers.

3.3. Reporting in accordance with Section 273 (2) and (3) Austrian Company Code UGB (exercising the duty to report)

During our audit we did not note any facts which indicate there could be substantial doubt about the Company's ability to continue as a going concern, or which indicate a material deterioration of the Company's performance or a material offence of the Director General or its employees against Austrian law or the Company's articles of association. We did not note any material weaknesses in the internal controls over the financial reporting process. The financial statements do not meet the requirements for the assumed need of reorganization in accordance with Section 22 Paragraph 1 Subsection 1 URG (Austrian Corporate Restructuring Act).
4. AUDITOR’S REPORT

Report on the Financial Statements

Audit Opinion

We have audited the financial statements of

Biobanking and BioMolecular resources Research Infrastructure -
European Research Infrastructure Consortium (BBMRI-ERIC), Graz,

These financial statements comprise the balance sheet as of December 31, 2018, the income statement for the fiscal year then ended and the notes.

Based on our audit the accompanying financial statements were prepared in accordance with the legal regulations and present fairly, in all material respects, the assets and the financial position of the Company as of December 31, 2018 and its financial performance for the year then ended in accordance with Austrian Generally Accepted Accounting Principles.

Basis for Opinion

We conducted our audit in accordance with Austrian Standards on Auditing. Those standards require that we comply with International Standards on Auditing (ISA). Our responsibilities under those regulations and standards are further described in the "Auditor’s Responsibilities for the Audit of the Financial Statements" section of our report. We are independent of the Company in accordance with the Austrian General Accepted Accounting Principles and professional requirements and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibility and liability as auditor is guided by Section 275 par. 2 Austrian Company Code UGB (liability regulations for the audit of small and medium-sized companies) and is limited to a total of 2 million Euros towards the Company and towards third parties.

Responsibilities of Company's legal representative for the Financial Statements

The Company's legal representative is responsible for the preparation of the financial statements in accordance with Austrian Generally Accepted Accounting Principles, for them to present a true and fair view of the assets, the financial position and the financial performance of the Company and for such internal controls as management determines are necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.
In preparing the financial statements, management is responsible for assessing the Company’s ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Auditor’s Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor’s report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Austrian Standards on Auditing, which require the application of ISA, always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with Austrian Standards on Auditing, which require the application of ISA, we exercise professional judgment and maintain professional scepticism throughout the audit.

We also:

- identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
TRANSLATION

- conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.

- evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

Comments on the Management Report

Pursuant to Section 243 (4) UGB the audited company did not prepare a management report.

Vienna, April 30, 2019

Ernst & Young
Wirtschaftsprüfungsgesellschaft m.b.H.

Erich Lehner m.p. Gerald Stockbauer m.p.
Wirtschaftsprüfer / Certified Public Accountant Wirtschaftsprüfer / Certified Public Accountant

*) This report is a translation of the original report in German, which is solely valid. Publication or sharing with third parties of the financial statements together with our auditor's opinion is only allowed if the financial statements are identical with the German audited version. This audit opinion is only applicable to the German and complete financial statements with the management report. Section 281 paragraph 2 UGB (Austrian Company Code) applies to alternated versions.
Legal Notice

Director General
Erik Steinfelder

Legal Address
BBMRI-ERIC
Neue Stiftingtalstrasse 2/B/6
8010 Graz, Austria
Phone: +43 316 34 99 17-0
Fax: +43 316 34 99 17-99
Email: contact@bbmri-eric.eu

Vat Number
ATU 68520549

Bank Details
Name of bank: Hypo Steiermark
IBAN: AT55 5600 0201 4139 7630
BIC: HYSTAT2G

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Name
Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC)

Legal Entity
European Research Infrastructure Consortium (ERIC)

Entry Into Force
On November 30, 2013, the BBMRI-ERIC Statutes were published in the Official Journal of the European Union and entered into force three days after publication on 3 December 2013. As from this date, the Biobanking and Biomolecular resources Research Infrastructure (BBMRI) was officially awarded the Community legal framework for a European Research Infrastructure Consortium (ERIC) and is henceforth to be called BBMRI-ERIC.

Philosophy, Nature and Purpose of Business
BBMRI-ERIC is designed to facilitate the joint establishment and operation of research infrastructures of European interest. The ERIC status allows pulling together biobanks and biomolecular resources into a pan-European facility and providing access to collections of partner biobanks and biomolecular resources, their expertise and services on a non-economic basis. BBMRI-ERIC is established for an unlimited period of time.

Court Jurisdiction
Court of Justice of the European Union

Liability
Members of BBMRI-ERIC

Procurement and Tax Exemption
BBMRI-ERIC benefits from tax exemption as outlined in Article 6 of the BBMRI-ERIC Statutes.

Members
Kingdom of Belgium, Republic of Bulgaria, Czech Republic, Federal Republic of Germany, Republic of Estonia, Hellenic Republic, French Republic, Italian Republic, Republic of Latvia, Republic of Malta, Kingdom of the Netherlands, Kingdom of Norway, Republic of Austria, Republic of Poland, Republic of Finland, Kingdom of Sweden, United Kingdom of Great Britain and Northern Ireland

Observers
Republic of Cyprus, Swiss Confederation, Republic of Turkey, International Agency for Research on Cancer (IARC/WHO)

Values
The activities of BBMRI-ERIC shall be politically neutral and guided by the following values: pan-European in scope, combined with scientific excellence, transparency, openness, responsiveness, ethical awareness, legal compliance and human values.