

## DATA TRANSFER AGREEMENT

(hereinafter referred to as: "Agreement")

- BETWEEN:** (1) **Breast International Group (BIG) aisbl, (VAT number BE 0468 176 240)** an international non-profit organisation organized and existing under the laws of Belgium, having its registered office at Rue de Bretagne 20 Bretnestraat, 1200 Brussels, Belgium,  
represented for the purposes of this Agreement by Theodora Goulioti, MD, Chief Executive Officer  
(hereinafter referred to as "BIG");
- AND:** (2) **[name of the recipient or the recipient's representing institution]**, having its registered office at **[address of the representing institution]**, represented for the purposes of this Agreement by **[name and function of the institution representative]**;  
(hereinafter referred to as "Recipient");

BIG and the Recipient are hereafter together also referred to as the "Parties" and individually as a "Party".

### INTRODUCTION

The following terms and conditions govern access to the personal data from the manuscript "Genomic and transcriptomic analyses of breast cancer primaries and matched metastases in AURORA, the Breast International Group (BIG) molecular screening initiative" (the "Manuscript"), published in the journal Cancer Discovery and hereinafter referred to as "Manuscript Data" for the only purpose of replicating and verifying the analyses performed in the Manuscript ("Purpose").

**NOW, THEREFORE, the Parties hereby agree as follows:**

### GENERAL OBLIGATIONS OF THE RECIPIENT

1. The Manuscript Data are stored by BIG and are provided to the Recipient exclusively for the Purpose described above, subject to the terms of this Agreement. This means that the use of these data for other purposes, such as the investigation or verification of other research questions are forbidden. The Manuscript Data will be delivered in trust to the Recipient and can be used for a maximum of

one (1) year after its reception. Any use of the Manuscript Data for a different purpose will need to be approved under a new agreement.

2. You and/or your institution shall hold and maintain and shall ensure that all employees and/or agents at all times hold and maintain in confidence all Manuscript Data.
3. The Manuscript Data may not be sold, assigned or transferred to any other party (other than assignment and/or transfer to researchers at your Institution working with you on the Manuscript analyses replication). Your institution and/or you shall assume all responsibility for the safe use and handling, in compliance with this Agreement and all applicable laws, of the Manuscript Data by you and/or your institution's employees or agents after the Manuscript Data have been provided to you and/or your institution. BIG is not responsible or liable for any claims arising from yours and/or your institution's use of these Manuscript Data.
4. The use of Manuscript Data shall be done in compliance with all international and national applicable laws and regulations including without limitation the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679 repealing Directive 95/46/EC).
5. It is recognized and understood that may exist certain previous inventions and technologies ("Background Intellectual Property") and that nothing in this Agreement shall operate to transfer to the Recipient any intellectual property rights to the Manuscript Data. Furthermore, the Recipient agrees not to generate or make intellectual property claims on the Manuscript Data.
6. For the avoidance of doubt, the Recipient agrees he/she is not acquiring any rights, title, or interest whatsoever in respect of the Manuscript Data at all times, except for the limited use as agreed upon in this Agreement.
7. The Manuscript Data are provided "as is", without warranty of any kind express or implied or statutory. BIG makes no representation or warranty that the use of the Manuscript Data shall not infringe any third party rights.
8. The Manuscript Data disclosed or otherwise made available to you or your Institution will not include any code or information allowing direct identification of the AURORA Program participants (hereafter "Data Subjects"). Further, you and/or your institution herewith represent and warrant that you will not undertake any actions to determine the identity of Data Subjects concerned, or to get access to any code allowing identification of Data Subjects.
9. To the extent authorized by laws, the Recipient hereby agrees to defend, indemnify and hold harmless BIG, its affiliates and its trustees, officers, employees, trainees and appointees from and against any liability or claim arising from any use of the Manuscript Data by him/her and/or his/her institution. BIG shall not be liable for any use by the Recipient of the Manuscript Data, nor any loss, claim, damage, or liability of whatsoever kind or nature which may arise from or in connection with this Agreement or the use of the Manuscript Data. In no event shall BIG be liable for indirect, special, punitive or consequential damages including but not limited to loss of use, loss of data and loss of profits or interruption of business.
10. BIG may terminate this Agreement immediately, upon written notice to the Recipient, in the event the Recipient is in breach of this Agreement. Otherwise, the Agreement shall terminate automatically twelve (12) months after the Effective Date.

11. The terms, provisions, representations, warranties and covenants contained in this Agreement that by their sense and context are intended to survive the performance thereof by the Parties hereunder shall so survive the completion of performance, expiration or termination of this Agreement.
12. Upon termination of your Manuscript analyses replication or upon termination of this Agreement for any reason, the Recipient shall destroy all Manuscript Data provided within the framework of this Agreement as well as any copy thereof in his/her possession and/or his/her your institution's possession.

### **DATA PROTECTION OBLIGATIONS**

13. The Parties agree on the following clauses on data protection in order to adduce adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals concerned for the transfer of the Manuscript Data as defined in the present Agreement.
14. Each party represents, warrants and undertakes to perform its obligations according to their respective responsibilities as defined in this Agreement, in accordance with data protection laws. For the purposes of this Agreement, BIG on one hand and the Recipient on the other shall act as independent Data Controllers of the Personal Data transferred related to the Manuscript analyses replication.
15. "Data Controller", "Data Processor", "Data Security Breach", "Personal Data", "Processing", "Technical and Organizational Measures", "Supervisory Authority" as well as the terms not defined in the following clauses related to data protection, shall have the meaning set forth in the General Data Protection Regulation (EU) 2016/679 with regard to the processing of personal data and on the free movement of such data.
16. The scope of the transfer of personal data is specified in the Exhibit A - DESCRIPTION OF THE TRANSFER OF PERSONAL DATA, which forms an integral part of this Agreement.
17. The Recipient agrees and warrants that:
  - (a) The Processing of Personal Data must be restricted to the Purpose and in with all applicable laws and regulations including, without limitation, General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679), including any future enactments thereof. If the Recipient cannot provide such compliance for whatever reasons, the Recipient agrees to inform promptly BIG of the Recipient's inability to comply, in which case BIG is entitled to suspend the transfer of data and/or terminate the Agreement;
  - (b) The Recipient has implemented the Technical and Organizational Measures before Processing the Personal Data transferred.
18. Further obligations of the Recipient:

The Recipient further agrees and warrants:

  - (a) that the Recipient shall not assign any Processing activity linked to the object of the present Agreement to a third Party;

- (b) that persons authorized to Process the Personal Data are bound by confidentiality obligations in relation to such Personal Data;
- (c) that the Recipient shall notify BIG within five (5) business days if the Recipient receives any communication from an individual or authority relating to Personal Data. The Recipient shall not respond to any such request unless obligated to do so under applicable laws or requested to do so by BIG. The Recipient shall provide reasonable and timely assistance to help BIG to respond to any such requests related to Personal Data where BIG has a legal obligation to respond within a given timeframe;
- (d) that the Recipient shall assist BIG by appropriate Technical and Organizational Measures, for the fulfilment of BIG's obligation to respond to requests for exercising the Data Subject's rights;
- (e) that the Recipient shall cooperate with BIG in order to assist BIG in assuring compliance with BIG's obligations under applicable laws regarding the deletion of Personal Data, following article 12 of the present Agreement, after completion of the approved Manuscript analyses replication or after expiration of the Agreement;
- (f) that at the request of BIG, the Recipient shall submit sufficient information about the Processing activities covered by this Agreement in order to demonstrate compliance and shall contribute to audits and/or inspections which shall be carried out by BIG or another auditor mandated by BIG. In case of audits conducted by BIG, such audits shall be done at BIG's own expense and will be notified to the Recipient with reasonable prior notice. Audits at the request of a data protection Supervisory Authority may be requested at any point in time by the data protection Supervisory Authorities or following a Data Security Breach. Following an audit conducted by data protection Supervisory Authority, if applicable, BIG shall notify the Recipient of the manner in which the Recipient does not comply with any of these clauses. Upon such notice, Recipient shall make any necessary changes to ensure compliance with such obligations;
- (g) to handle promptly and properly all inquiries from BIG relating to the Recipient's Processing of the Personal Data subject to the transfer and to abide by the advice of any Supervisory Authority with regard to the Processing of the Personal Data transferred;

#### 19. Security of Processing

- (a) Recipient shall implement appropriate Technical and Organizational measures to ensure a level of security appropriate to the risk for the Personal Data transferred, such as pseudonymisation, back-up or disaster recovery.
- (b) Recipient shall notify BIG within forty-eight (48) hours of becoming aware of any Data Security Breach and such notification will include, where possible, the approximate number of Data Subjects concerned and approximate number of Personal Data concerned, the impact and likely consequences on BIG and the corrective action to be taken by the Recipient.
- (c) Recipient shall promptly implement, at Recipient's expense (to the extent that the Data Security Breach was due to a breach of obligations under this Agreement or applicable laws),

all corrective measures to necessary remedy the causes of such a breach and shall consult in good faith with BIG as regarding what remediation efforts may be necessary.

- (d) Recipient shall ensure that such remedy efforts provide for, without limitation, prevention of the recurrence of the same type of Data Security Breach and inform BIG of all corrective measures implemented and remediation efforts undertaken.

## **FINAL PROVISIONS**

20. You and/or your Institution's acceptance of the terms identified above is acknowledged by the signature of the present Agreement. The Recipient must not use the Manuscript Data until all actions necessary to implement the legal terms set forth above has been taken and accepted by the signature below.

21. This Agreement shall be governed and construed in accordance with the laws of Belgium. The Parties shall endeavor, in good faith, to settle any and all disputes amicably. In the event of any dispute, difference, controversy or claim arising out of or in connection with this Agreement, the Parties shall first attempt to settle such dispute by consultations in at least two (2) meetings on the subject. If the Parties have not reached a settlement of such dispute at the expiration of sixty (60) days after the second meeting, the dispute shall be finally settled by the exclusive competent courts of Brussels, Belgium.

22. EXHIBIT A – Description of the transfer of personal data is understood to form an integrated part of this Agreement.

## **SIGNATURES**

23. The Parties agree that this Agreement will become effective and binding as from the date of the last signature ("Effective Date"). The Parties expressly recognize electronic signature to be a valid signature of this Agreement.

### **For BIG,**

Name: Theodora Goulioti, MD

Title: CEO

Date:

Signature:

### **For the Institution representing the Recipient, [if applicable]**

Name:

Title:

Date:

Signature:

**For the Recipient:**

Name:

Title:

Date:

Signature:

## Exhibit A

### DESCRIPTION OF THE TRANSFER OF PERSONAL DATA

#### Data subjects

The personal data transferred concern the following categories of data subjects:

- AURORA Program Participants

#### Purposes of the transfer(s)

The transfer is made for the following purposes:

- Manuscript results replication and verification

#### Categories of data

The personal data transferred concern the following categories of data:

- Clinical Data
- Molecular Data

#### Recipients

The Personal Data transferred may be disclosed only to the following recipients or categories of recipients:

- The Parties to the Agreement and their employees/collaborators directly involved in the activities foreseen in the Agreement

#### Sensitive data (if appropriate)

The personal data transferred concern the following categories of sensitive data:

- Clinical Data
- Molecular Data

#### Additional useful information (storage limits and other relevant information)

Recipient will keep the Personal Data as long as required for the performance of the Manuscript results replication and verification or, in any case, for a maximum of one (1) year after the reception of the data.

#### Contact points for data protection enquiries

##### Recipient

**[To be completed]**

**BIG**

BIG Data Protection Officer

[dpo@bigagainstbc.org](mailto:dpo@bigagainstbc.org)

Rue de Bretagne 20 Bretnestraat,

1200 Brussels, Belgium