

## Collaboration Agreement

This Agreement is entered into by and between:

**ATOS SPAIN, S.A.** (formerly **ATOS ORIGIN, S.A.E.**) a Spanish corporation having its registered office at Albarracín, nº 25, Madrid (Spain) (hereinafter called "**ATOS** "),

acting on its behalf and regarding the acceptance of ROCHE in the Advisory Boards on behalf of the following participants of the EU project **REACTION**, Grant Agreement Number FP7 248590:

1. CNET SVENSKA AB
2. DANISH ELECTRONICS, LIGHT & ACOUSTICS
3. INSTITUT FUER MIKROTECHNIK MAINZ GMBH (IMM)
4. FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS
5. FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V. as legal entity for its FRAUNHOFER INSTITUTE FOR SECURE INFORMATION TECHNOLOGY SIT
6. HELLENIC TELECOMMUNICATIONS & TELEMATICS APPLICATIONS COMPANY
7. IN-JET APS
8. APPLIED LOGIC LABORATORY
9. MEDIZINISCHE UNIVERSITAT GRAZ (MUG)
10. JOANNEUM RESEARCH FORSCHUNGSGESELLSCHAFT MBH (JRF)
11. CHORLEYWOOD HELATH CENTRE
12. BRUNEL UNIVERSITY (BRUNEL)
13. VRIJE UNIVERSITEIT BRUSSEL
14. BAYER TECHNOLOGY SERVICES GMBH (BTS)

(hereinafter called the "Consortium"),

**AND**

**Roche Diagnostics GmbH**, a German corporation having its registered office at Sandhofer Straße 116, 68305 Mannheim / Germany, hereinafter referred to as "**ROCHE**"

**AND**

1. **BAYER TECHNOLOGY SERVICES GMBH**, a German corporation having its registered office at Kaiser Wilhelm Allee, 51368 Leverkusen / Germany, hereinafter referred to as "**BTS**"
2. **INSTITUT FUER MIKROTECHNIK MAINZ GMBH**, a German corporation having its registered office at Carl-Zeiss- Str. 18-20, 55129 Mainz / Germany, hereinafter referred to as "**IMM**"
3. **JOANNEUM RESEARCH FORSCHUNGSGESELLSCHAFT MBH**, an Austrian research centre having its registered office at Leonhardstrasse 59, 8010 Graz / Austria, hereinafter referred to as "**JRF**".
4. **BRUNEL UNIVERSITY**, an UK University, which legal address is Kingston Lane, Uxbridge, UB8 3PH, UK, hereinafter referred to as "**BRUNEL**".

(hereinafter, jointly or individually, referred to as "Acceding Party" or "Acceding Parties")

## WITNESSETH

**WHEREAS, ATOS** is the Coordinator of the Project REACTION (Remote Accessibility to Diabetes Management and Therapy in Operational healthcare Regimes), hereinafter called "the Project", that has been granted with public funds under the FP7 of the European Commission; and

**WHEREAS, ATOS** and the other companies of the Consortium have signed a Consortium Agreement to regulate the execution of the Project; and

**WHEREAS**, the Consortium is expected to set up the collaboration with external companies which activity or experience are directly linked with the purposes of the Project; and

**WHEREAS, ROCHE** is a relevant representative in the field of Pharmacy and Devices, and agrees to participate and contribute to the Project as defined below; and

**WHEREAS, ROCHE** is willing to become a member of the Technical Advisory Board and the Medical Advisory Board set up by the Consortium in the Project, where external members are invited to provide feedback about matters related to the purpose of the Project and to support the Project as defined in this Collaboration Agreement;

**WHEREAS, ROCHE** is the owner of the "Pump Protocol" and is willing to grant access rights to such ROCHE IP to some members of the Consortium (hereinafter "the Acceding Parties") under the terms and conditions to be agreed in private individual contracts between ROCHE and each of the Acceding Parties based on this Collaboration Agreement.

WHEREAS, ROCHE and ATOS (on behalf of the Consortium) have signed a Confidential Disclosure Agreement stating the confidentiality provisions to be applied in the disclosure of Confidential Information between ROCHE and the Consortium.

**ATOS and ROCHE hereby agree as follows:**

### 1. Definitions.

"**Effective Date**" shall be 01<sup>st</sup> of March 2013.

"**ROCHE IP**" shall mean the pump protocol or Connectivity Kit, which consists of source code. The source code can be transferred by means of two different packages. Package 1, for PC/XP can be sent by email. Package 2 can handle only one pump and can be transferred by means of a DVD? Limited support from ROCHE is offered to help understanding how the code works.

"**FOREGROUND**" according the rules of the REACTION Consortium Agreement of the Project means the results, including information whether or not they can be protected, which are generated under the REACTION Project. Such results include rights related to copyright, design rights, patent rights or similar form of protection.

### 2. ROCHE Membership of REACTION Advisory Boards.

ATOS in its responsibility as Coordinator of the REACTION project hereby confirms that the Consortium has decided to accept ROCHE as Member of the Technical Advisory Board and the Medical Advisory Board and therefore will invite ROCHE to participate in the meetings to be held from the Effective Date on.

### 3. Access to ROCHE IP.

ROCHE hereby grants to the Acceding Parties a non-exclusive, worldwide, irrevocable right in the ROCHE IP for the purpose of executing the Acceding Parties' tasks under the Project where

Needed (as defined in the Acceding Parties Consortium Agreement) as described in Section 4. For the sole research and development purposes and scope of the Project the license granted herein shall be royalty-free. The commercial terms (including fair and reasonable licence fees, security issues in case of use, conditions for sublicenses, etc.) for any use outside the Project and future use, commercialization or exploitation of Foreground generated under the Project shall be negotiated by and between ROCHE and every single Acceding Party on a case-by-case basis individually.

The terms of such private agreements will not affect the Consortium's rights and obligations described in both the Grant Agreement and the Consortium Agreement.

The right and license granted herein by ROCHE to the Acceding Parties shall be conditional to the respective Acceding Party's signature of this Collaboration Agreement.

Apart from the Acceding Parties, no other beneficiaries of the Consortium will have access or use in any way ROCHE IP.

#### **4. Purpose and Scope of Access to ROCHE IP within the Project.**

The access to and use of the ROCHE IP for the purpose and scope of the Project is strictly restricted to specific tasks to be performed within "WP3 – Sensors, Monitoring and Contextualisation" of the REACTION Project. This Collaboration Agreement therefore involves only a limited number of beneficiaries out of the Consortium and not the whole consortium. According to the definition of FOREGROUND in Section 1, the work carried out in the tasks that relate to ROCHE's IP is exclusively property of the Consortium partners involved in those tasks.

The major objective of the requested access to ROCHE IP in the Project is to optimise the interface between the AGC algorithm and the insulin pump itself, rather than optimising the pumps performance or their hardware communication interface. Based on the sensor data generated from the individual sensors an optimised insulin dose has to be delivered by the pump.

##### **Phase 1 - no access or use of ROCHE IP:**

1. Medizinische Universität Graz (MUG) plans to test the algorithm developed by Bayer Technology Services (BTS) using in vivo experiments in carefully controlled laboratory conditions where best quality glucose measurements are used. The new insulin dose using the algorithm is calculated and insulin delivery on a commercially available pump is manually altered. Data may be used for further simulation and evaluation, such as perturbing the accuracy of the glucose measurement, adding delay to simulate interstitial changes, etc. MUG provides only the environment and facilities to test the equipment/devices/components which will be provided by the partners (BTS: Algorithm, IMM: sensor + pump). MUG will not be involved in the development of the interface between sensor-algorithm-pump; this means that MUG will not have access to the ROCHE IP provided by Roche nor will directly benefit using the IP-protocol.
2. If satisfactory performance from CGM sensors developed by Institut für Mikrotechnik Mainz (IMM) and Joanneum Research Forschungsgesellschaft (JRF) is achieved, they can be coupled in place of the best glucose measurement system commercially available.
3. At this point, the plan is to make IMM/JRF - CGM sensors communicate with the BTS algorithm, which in turn should be able to activate the commercially available insulin pump.

##### **Phase 2 - access and use of ROCHE IP:**

4. Therefore, the objective is to demonstrate that the algorithm developed by BTS in REACTION is able to be made to have direct control over Roche's Accu-Chek Combo™ insulin pump by using the ROCHE IP. Therefore IMM/JRF will use the ROCHE IP to implement a prototype able to automatically activate Roche's Accu-Chek Combo™ insulin pump based on the outputs of the BTS algorithm.

5. Brunel University (BRUNEL) might develop embedded controllers to communicate between an insulin pump and other devices, including continuous glucose monitors.

Phase 3 – no access or use of ROCHE IP:

6. MUG might then test the integrated system (IMM/JRF sensors + system running the BTS algorithm and giving orders via PC to commercially available pumps) in a controlled environment and will report malfunction of the system to the technical partners if any.

**5. Access Rights to ROCHE in the Foreground.**

The Acceding Parties hereby agree to grant to ROCHE upon written request of ROCHE a non-exclusive right in their own FOREGROUND under fair and reasonable conditions in case the FOREGROUND constitutes an improvement or continuation or continuation in part of the ROCHE IP and in case it has been generated in the PROJECT by the Acceding Parties based on the use of the ROCHE IP.

The right granted herein to ROCHE by the respective Acceding Party shall be conditional to the respective Acceding Party's signature of this Collaboration Agreement.

**6. No Warranty.**

ROCHE DISCLAIMS ANY AND ALL WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE ROCHE IP, ITS CONTENTS OR ANY PRODUCTS OR SAMPLE PRODUCTS OR ANY USE OF PRODUCTS OR SAMPLE PRODUCTS IN CONJUNCTION WITH the ROCHE IP. IN NO EVENT SHALL ROCHE OR ITS AFFILIATES BE LIABLE FOR ANY DAMAGES WHATSOEVER INCLUDING, BUT NOT LIMITED TO INCIDENTAL, SPECIAL, DIRECT, INDIRECT OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE USE OR INABILITY TO USE THE ROCHE IP OR ANY PRODUCT EVEN IF ROCHE OR THE RELEVANT AFFILIATE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. DEVELOPMENT, DESIGN, MANUFACTURE, VALIDATION, EVALUATION, USAGE, MODIFICATION AND/OR ADAPTATION OF THE PROPRIETARY SOFTWARE SUPPORTING THE ROCHE IP OR PARTS THEREOF SHALL AT ALL TIMES REMAIN THE EXCLUSIVE RESPONSIBILITY OF THE RESPECTIVE ACCEDING PARTIES OR ITS PARTNERS.

**7. Indemnification.**

The Acceding Parties shall protect, indemnify, defend and hold harmless ROCHE and its Affiliates and each of their respective directors, officers, employees, and agents, and their respective successors and permitted assigns from and against any and all claims, actions, causes of action, losses, liabilities or damages, including reasonable attorneys' fees, which directly or indirectly arise out of or relate to (a) any breach by the Acceding Parties of this Agreement, (b) any use or misuse of the data transferred by using the ROCHE IP, (c) the ROCHE IP, including any developments, evaluation, usage, modification, adaptation, sale, and/or distribution of the ROCHE IP or any other activities relating to the ROCHE IP, (d) any interference by the ROCHE IP with the functions or operation of the Products, sensors or algorithms, ((f) any malfunction of Products or Sample Products caused by or contributed to by the ROCHE IP or the actions or omissions of Acceding Parties or any third party, (g) any other activities which are Acceding Parties responsibility under this Agreement.

**8. Duration and Termination.**

This Collaboration Agreement shall have effect, upon signature by all Parties, from the Effective Date and shall continue in full force and effect until termination of the Grant Agreement or the Consortium Agreement,

However, any Party may terminate this Agreement at any time by thirty (30) days written notice. The Parties may also extend the duration by written agreement.

**9. Amendment.**

This Agreement may not be changed or modified except in writing signed by all Parties.

**10. Applicable Law.**

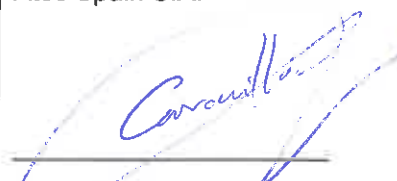
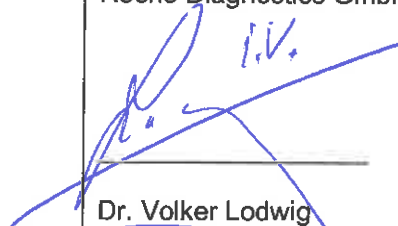
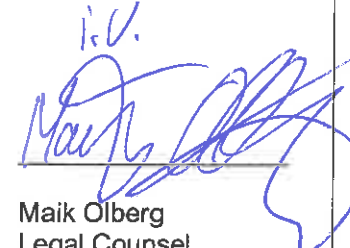
This Agreement shall be governed and construed in accordance with the laws of Belgium.

**11. Dispute Resolution and Jurisdiction.**


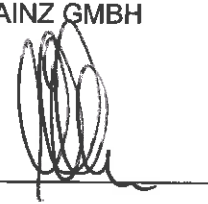

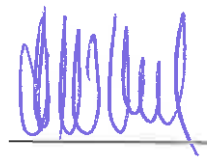
Parties agree to a good faith attempt to settle as promptly as possible any and all disputes arising from transactions pursuant to this Agreement. In the event that efforts to settle a dispute arising under this Agreement are not successful, the Parties agree to the exclusive jurisdiction of the competent courts in Brussels, Belgium, with the exclusion of any other jurisdiction or arbitration.

The Parties hereto have caused this Agreement to be executed by their duly authorized representatives.

**For ATOS and ROCHE:**

<p>Date and place: <u>27/06/2013 MADRID</u></p> <p>Atos Spain S.A.</p>  <p>Josema Cavanillas Research and Innovation Director</p>	<p>Date and place: <u>03/07/2013</u></p> <p>Roche Diagnostics GmbH</p>  <p>Dr. Volker Lodwig Head of Medical Device Technologies &amp; Governmental Affairs Medical Affairs</p>  <p>Maik Olberg Legal Counsel</p>
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**For the Acceding Parties:**

<p>Date and place: <u>Leuven 2013-05-28</u></p> <p>BAYER TECHNOLOGY SERVICES GMBH</p>  <p>Dr. Henning Lütjens Law &amp; Patents</p> <p>Dr. Michael Heite Head of T&amp;I</p>	<p>Date and place: <u>Mainz, 04 June 2013</u></p> <p>INSTITUT FÜR MIKROTECHNIK MAINZ GMBH</p>  <p>Prof. Dr. Michael Maskos CEO</p>	<p>Date and place: <u>18/06/13 London</u></p> <p>BRUNEL UNIVERSITY</p>  <p>Adam Bell Head, Contracts and Intellectual Property Research Support and Development Office</p>	<p>Date and place: <u>Graz, 13.6.2013</u></p> <p>JOANNEUM RESEARCH Forschungs GmbH</p>  <p>Prof. Dr. Wolfgang Pribyl Managing Director</p>
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Institut für Mikrotechnik Mainz GmbH  
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