

## **Brucellosis Vaccine Prize - Competition Rules**

### **1 Introduction and Background**

- 1.1 These terms and conditions (the "**Rules**") govern applications to and participation in The Brucellosis Vaccine R&D Pilot Initiative (the "**Competition**") funded by AgResults (a collaborative multi-donor initiative between the Australian, Canadian, UK and US governments and the Bill & Melinda Gates Foundation) ("**AgResults**") and managed by the Global Alliance for Livestock Veterinary Medicines (a charity registered in Scotland under number SC039197) with offices at Doherty Building, Pentlands Science Park, Bush Loan, Edinburgh, EH26 0PZ, UK ("**GALVmed**").
- 1.2 The purpose of the Competition is to encourage the development of an improved, safe, low-cost, and efficacious vaccine for *Brucella melitensis* ("**Brucellosis**") in small ruminants, which is granted a marketing authorization (subject to the requirements set out below) and fulfills minimum quality criteria (as further described below).
- 1.3 The Rules are a binding legal agreement between GALVmed and the organization submitting the application to the Competition as identified at the end of these terms and conditions (the "**Solver**"). Applications will not be eligible unless the eligibility criteria in Section 2 (Application eligibility) are satisfied. Furthermore, in order for an application by a Solver to be eligible for the Competition, the Rules must be signed on behalf of the Solver where indicated at the end of these Rules and returned to GALVmed in accordance with these Rules.
- 1.4 By signing and returning the Rules, the Solver agrees: (a) to comply with the Rules when participating in the Competition; (b) that once duly executed, the Rules will constitute a legal, valid and binding agreement; (c) it has full capacity and authority to enter into the Rules; and (d) the Rules have been executed by a duly authorized representative of the Solver.
- 1.5 Other than as stated herein (including without limitation the confidentiality obligations which shall continue in accordance with Section 10 (Confidentiality)), the Rules shall remain in force until the Solver no longer has any involvement with the Competition.
- 1.6 For the purposes of the Rules, the "AgResults Entities" means GALVmed's partner organizations and governmental bodies working with and/or providing funding for GALVmed in relation to the Competition (including without limitation the Bill & Melinda Gates Foundation, the governments of Australia, Canada, the UK, the USA, and the organization acting as the Secretariat for AgResults from time to time).
- 1.7 All individuals working directly for GALVmed and/or any of the AgResults Entities as well as their family members, are excluded from participating in the Competition.

### **2 Application eligibility**

Application to the Competition is open to organizations with demonstrable experience and expertise of all of the following: researching, developing, registering, manufacturing and

commercializing animal health vaccines. However, if any applicant Solver is only able to satisfy all of the foregoing criteria by partnering with a third party organization which has the required experience and expertise, this is also permitted subject to compliance with the rest of the terms and conditions set out in the Rules below. Academic or purely research organizations are permitted to submit applications to the Competition as part of Phase 1 (as described below) and may participate in Phase 2 of the Competition (providing that their Application is accepted in accordance with these Rules). However, in order to be eligible to receive Milestone Payment 2 (as part of Phase 2) and to progress to Phase 3 of the Competition as further described below, any academic or purely research organizations will need to provide evidence of support and commitment from a commercial organization which has the experience and expertise referred to above. A signed letter of commitment or similar legally binding document is acceptable to provide such evidence. Applications by individuals are not permitted.

- 2.1 Solvers may make multiple Applications to the Competition provided that any such Applications are based on the use of sufficiently different concepts and/or technologies in relation to the development of a vaccine for Brucellosis, as determined by the Judging Panel in its sole discretion as described further below in these Rules.

### **3 Phases and Competition structure**

- 3.1 The Competition is structured in the following 3 phases (the "**Phases**"):

Phase 1: The Application Phase starting on November 18th, 2016 (the "**Application Start Date**") and leading up to the potential award of Milestone Payment 1 as further described below.

Phase 2: The Solving Phase starting for each Solver upon successful application and leading up to the potential award of Milestone Payment 2 as further described below.

Phase 3: The Final Phase starting for each Solver upon successful application and completion of Phase 2 and leading up to the potential award of a Prize as further described below.

Except as described in the Rules below, Solvers will not be eligible to participate in: (a) Phase 2 unless they have successfully applied and registered as Solvers (as part of Phase 1) and the Solver has been selected to progress to Phase 2 in accordance with these Rules; and (b) Phase 3 unless Phase 2 has been successfully completed and the Solver has been selected to progress to Phase 3 in accordance with these Rules.

- 3.2 Notwithstanding the foregoing, Solvers are entitled to submit their Application at any time until the Final Application Deadline (as described in Section 5.1.1 below) and if their Application is accepted in accordance with these Rules, may at the Solver's election move straight to Phase 3 as described in Section 6.3.6 below.
- 3.3 Solvers will be required to comply with various timeframes and deadlines in relation to each Phase as further described in the Rules. Solvers agree that failure to comply with any such timeframes and deadlines may result in the Solver being disqualified from participation in the Competition at the sole discretion of GALVmed.
- 3.4 Solvers further acknowledge and agree that the timeframes and deadlines applicable to each Phase may be extended by GALVmed at GALVmed's sole discretion dependent, for example, on the number of Applications received and the speed with which Solvers participating in the Competition progress through the various Phases. Any extensions to Phases as described in this section will apply to all participating Solvers equally.

3.5 For the avoidance of doubt, Milestone Payments (as defined below) and Prizes (as defined below) will only be paid to the nominated bank account of the applicable Solver and will not be paid to any individuals within any Solver organization. In relation to consortium Applications as described in Section 5 below (Phase 1: The Application Phase), Milestone Payments and Prizes will be paid to the applicable primary Solver as identified in the Application and not to any other organization within the consortium and it is the responsibility of the consortium to determine how the relevant Milestone Payments and Prizes are divided between them.

#### **4 Judging Panel**

4.1 A panel of 5 judges (the "**Judging Panel**") appointed by GALVmed, will be responsible for determining whether Solvers are successful in each Phase as described below and are entitled to progress to the next Phase and receive a Milestone Payment (as defined below) or a Prize (as defined below) as applicable.

4.2 The Judging Panel will consist of experts with experience in the field of animal health biological research and development, technical vaccine research and development, Brucellosis and its impacts, regulatory affairs, marketing authorization applications for veterinary vaccines, vaccine marketing and vaccine commercialization.

4.3 The Solver acknowledges and agrees that any member of the Judging Panel may be replaced or removed by GALVmed at any time without notice.

4.4 The names of the individual members of the Judging Panel at any time during the Competition will be made available at the reasonable request of a Solver. Without prejudice to the foregoing, Solvers acknowledge and agree that they will not contact Judging Panel members directly and that any/all correspondence and enquiries regarding the Competition must be sent to GALVmed. GALVmed reserves the right to disqualify the Solver from the Competition in the event the Solver breaches this section.

4.5 Subject to section 15 (Dispute Resolution), the decisions of the Judging Panel and GALVmed will be final and binding in all aspects of the Competition.

4.6 GALVmed (including where GALVmed is acting on the Judging Panel's behalf) shall be entitled, throughout each Phase of the Competition, to ask Solvers clarification questions and/or request additional information from the Solvers in order to assist with the evaluation and assessment processes described below. The Solvers will respond to such questions and provide such additional information as soon as reasonably practicable and within any timeframes specified by GALVmed. If any such questions are not answered and/or information provided within any such specified timeframes, GALVmed reserves the right to disqualify the Solver from the Competition.

4.7 Solvers acknowledge and agree that GALVmed will not provide technical assistance to Solvers, but will instead share general, non-proprietary/non-confidential information, as appropriate, equally with all Solvers. GALVmed may, for example, distribute information in writing to all Solvers regarding financing opportunities or lessons learned regarding the vaccine research and development process.

## 5 Phase 1: The Application Phase

### 5.1 Phase 1 Requirements and Structure

- 5.1.1 During Phase 1 of the Competition, Solvers submit their initial application to participate in the Competition (the "**Application**"). Applications can be made any time from the Application Start Date (i.e. November 18th 2016 up until either (a) 1 year following the successful award of the Grand Prize (as described below) or (b) ~~November~~ May 18th ~~2026~~2028, whichever occurs earlier (the "**Final Application Deadline**").
- 5.1.2 In order to be eligible to receive Milestone Payment 1 as described below, applications must be submitted before 23:59 Greenwich Mean Time (GMT) on November 18th 2017(the "**Milestone Payment 1 Closing Date**").
- 5.1.3 Applications received after the Milestone Payment 1 Closing Date (i.e. November 18 2017) will **not** be eligible for receiving Milestone Payment 1. In the event that the Milestone Payment 1 Closing Date (i.e. November 18 2017) is extended in accordance with section 3.4, any Solvers who have already submitted an Application will be entitled to withdraw and resubmit an amended or updated Application if they wish to do so prior to the new Milestone Payment 1 Closing Date as extended.
- 5.1.4 Applications submitted after the Milestone Payment 1 Closing Date (i.e. November 18th 2017) but before the Final Application Deadline (as described in Section 5.1.1) will **not** be eligible for receiving Milestone Payment 1, but may still be eligible to enter the Competition at that stage and participate in the Competition without receiving Milestone Payment 1.
- 5.1.5 Applications submitted after the Final Application Deadline (as described in Section 5.1.1) will not be eligible to enter the Competition.
- 5.1.6 Applications should be submitted to GALVmed either online via the website located at [www.brucellosisvaccine.org](http://www.brucellosisvaccine.org) (or such other website as may be notified by GALVmed) or via email to [brucellosis@galvmed.org](mailto:brucellosis@galvmed.org) (or such other email address as may be notified by GALVmed), in each case using the pro forma application form made available by GALVmed. Applications must include the following:
- (a) A scanned copy of these Rules signed in accordance with Section 1.4 of these Rules.
  - (b) The application form, with the mandatory information filled in either online, or in pdf format.
  - (c) Documented evidence of partner commitment as described in Section 2 of these Rules, where the Solver is not capable of developing the vaccine up to registration on its own.
- 5.1.7 The Application must be submitted in the English language. The Application must be complete, with all compulsory questions in the application form filled out.

- 5.1.8 Multiple organizations which satisfy the eligibility requirements in Section 2.1(Application eligibility) above may submit a joint Application as part of a consortium. In the case of any such consortium Application: (a) one organization must be identified in the Application as the primary Solver and will be the entity which enters into the Competition and signs these Rules on behalf of the consortium and receives on behalf of the consortium any Milestone Payments and/or Prizes (as defined below) for which the consortium will be eligible in accordance with these Rules, and (b) satisfactory evidence must be provided regarding the basis on which work will be allocated between the consortium members and how any/all intellectual property will be owned and/or managed as between the different members of the consortium. The primary Solver will be responsible and liable to GALVmed for the acts and omissions of the other members of the consortium.
- 5.1.9 During Phase 1, Solvers will have the opportunity to ask clarification questions to GALVmed in relation to the required format and content of the Application. The Solver acknowledges and agrees that the content of any such questions and the associated responses will not be treated as confidential and may be shared with other Solvers.
- 5.1.10 GALVmed reserves the right to close the Competition if no eligible Applications are received by November 18, 2017. In this case, this will be published on the website located at [www.brucellosisvaccine.org](http://www.brucellosisvaccine.org) and this deadline may be extended for up to 4 weeks at GALVmed's sole direction. If after such new deadline no eligible Applications are received, GALVmed reserves the right to close the Competition, and the Milestone Payments and Prizes may be used for other purposes at the discretion of the applicable donors.

## **5.2 Evaluation of Applications**

- 5.2.1 During Phase 1, on expiry of each quarter (i.e. 3 month period) from the Application Start Date (i.e. November 18th 2016) the Judging Panel will evaluate and assess the received Applications which comply with, and were submitted in accordance with, the Rules, to determine which Applications best meet the criteria set out in Appendix 1 (Application Criteria).
- 5.2.2 As part of the evaluation and assessment described above, the Judging Panel in its sole discretion will determine which Solvers should progress to the next Phase of the Competition and which such Solvers are eligible to receive a Milestone Payment 1 as described below.

## **5.3 Selection of Solvers and payments of Milestone Payment 1**

- 5.3.1 Following completion of each quarterly evaluation and assessment of the Applications by the Judging Panel as described above, GALVmed will notify the applicable Solvers no later than 30 working days following expiry of the applicable quarter whether their Application has been:
- (a) accepted with an award of Milestone Payment 1;

- (b) accepted but does not sufficiently satisfy the criteria set out in Appendix 1 (Application Criteria) to be eligible to receive Milestone Payment 1;
  - (c) accepted but an award of Milestone Payment 1 to be assessed following expiry of the next quarter of Phase 1 (unless the assessment occurred in the final quarter of Phase 1); or
  - (d) declined.
- 5.3.2 In relation to those Solvers who were notified that their Application has been accepted but an award of Milestone Payment 1 to be assessed following expiry of the next quarter of Phase 1 as described above; GALVmed will notify such Solvers within 90 days following expiry of the next quarter whether their Application is eligible to receive Milestone Payment 1.
- 5.3.3 Solvers whose Application has been accepted (regardless of whether Milestone Payment 1 has been awarded or not) will be entitled to progress to Phase 2 of the Competition.
- 5.3.4 Solvers whose Application has been declined are entitled to revise their Application and resubmit it in accordance with these Rules. There is no limit on the number of times a revised Application can be resubmitted prior to the Final Application Deadline (as described in Section 5.1.1).
- 5.3.5 There is no maximum number of Solvers who may be selected to progress to Phase 2 of the Competition, however as described below, **a maximum of 10 Solvers will be eligible to receive Milestone Payment 1.**
- 5.3.6 Up to 10 Solvers out of all the Solvers who submit Applications which are subsequently selected by the Judging Panel to progress to Phase 2 of the Competition may also receive Milestone Payment 1. GALVmed will inform all participating Solvers once all available Milestone Payments 1 have been awarded.
- 5.3.7 As described above, the decision whether to award a Milestone Payment 1 will occur on a quarterly basis. Once the maximum 10 Solvers have been awarded a Milestone Payment 1, no further Solvers will be eligible to receive a Milestone Payment 1 but may still submit an Application to participate in the subsequent Phases of the Competition in accordance with the Rules. Solvers are therefore advised to submit their Applications as early as possible to increase the chances of being eligible to receive a Milestone Payment 1.
- 5.3.8 When evaluating and assessing the Applications in order to determine their eligibility to receive Milestone Payment 1, the Judging Panel will base its decision, in the Judging Panel's sole discretion, on which Applications best satisfy the criteria set out in Appendix 1 (Application Criteria).
- 5.3.9 There is no minimum number of Solvers who may be selected to progress to Phase 2 and/or receive Milestone Payment 1. Therefore, in the event that the Judging Panel determines that no Applications sufficiently satisfy the evaluation criteria described above, no Solvers may be selected to progress to the next Phase

and/or receive Milestone Payment 1 and GALVmed shall be entitled to close the Competition as described in Section 5.1.10 above.

5.3.10 Milestone Payment 1 is a one-off payment of one hundred thousand US dollars (\$100,000). Only one Milestone Payment 1 is payable per Solver (irrespective of how many Applications that Solver has submitted).

## **6 Phase 2: The Solving Phase**

### **6.1 Phase 2 Requirements and Structure**

6.1.1 Once each Solver has been notified that its Application has been accepted, that Solver may proceed to Phase 2 (The Solving Phase).

6.1.2 For Phase 2, Solvers will be required to work towards the production of a proof-of-concept together with the other deliverables as outlined in Appendix 2 (the "**2nd Milestone Deliverables**").

6.1.3 Solvers will be required to present the 2nd Milestone Deliverables at the latest either (a) within 1 year following the successful award of the Grand Prize (as described below) or (b) by ~~October~~ April 30th ~~2026~~2028, whichever occurs earlier (this deadline also being referred to as the "**Phase 2 Closing Date**").

6.1.4 2nd Milestone Deliverables received after the Phase 2 Closing Date (as described in Section 6.1.3) will not be eligible. In the event that the Phase 2 Closing Date (as described in Section 6.1.3) is extended in accordance with section 3.4, any Solvers who have already submitted 2nd Milestone Deliverables will be entitled to withdraw and resubmit new or updated 2nd Milestone Deliverables if they wish to do so prior to the new Phase 2 Closing Date as extended.

6.1.5 2nd Milestone Deliverables should be submitted to GALVmed either online via the website located at [www.brucellosisvaccine.org](http://www.brucellosisvaccine.org) (or such other website as may be notified by GALVmed) or via email to [brucellosis@galvmed.org](mailto:brucellosis@galvmed.org) (or such other email address as may be notified by GALVmed).

6.1.6 The 2nd Milestone Deliverables shall be treated as Confidential Material (as defined below) of the Solver.

6.1.7 Following commencement of Phase 2 for each Solver, the Solver agrees to provide GALVmed with a report every 6 months setting out details of the Solver's progress towards completion of Phase 2. The report should be substantially based on the template report form set out in Appendix 5 (Template Report Form).

6.1.8 GALVmed will hold one-on-one meetings by teleconference or videoconference twice yearly with Solvers to discuss and monitor their progress in relation to Phase 2 and to answer Solver questions. The Solver acknowledges and agrees that, subject to the confidentiality obligations in respect of Confidential Material as described below, the content of any such questions and the associated responses may be shared with other Solvers to ensure that no Solver is given an advantage over any other Solver.

- 6.1.9 In the event that GALVmed determines, acting reasonably, and based on the information available to GALVmed, that a Solver is making insufficient progress towards completion of Phase 2, GALVmed will notify the Solver and the Solver shall produce and implement a remediation plan setting out details of the planned corrective actions or alternatively withdraw from the Competition pursuant to section 8.6.
- 6.1.10 In the event that no Solvers provide reports pursuant to section 6.1.7, GALVmed may elect to cancel the Competition on notice to all applicable Solvers as determined in its sole discretion.

## 6.2 Evaluation of 2nd Milestone Deliverables

- 6.2.1 On receipt of each eligible set of 2nd Milestone Deliverables from a Solver which comply with, and are submitted in accordance with, these Rules, the Judging Panel will evaluate and assess them to determine, in its sole discretion, whether the Solver's vaccine candidate has met or exceeded the target requirements and evaluation criteria set out in Appendix 2 (2nd Milestone Deliverables and Criteria). At the request of the Judging Panel, Solvers may be required to present their submissions in person if practicable or via video link to enable a full discussion of the data to allow the Judging Panel to best evaluate whether the criteria set out in Appendix 2 (the 2nd Milestone Deliverables) have been met.
- 6.2.2 Following completion of the Judging Panel's evaluation and assessment of each set of 2nd Milestone Deliverables as described above, GALVmed will notify the applicable Solver no later than 90 days after the Solver's submission of the 2nd Milestone Deliverables whether it has succeeded or failed in achieving the criteria set out in Appendix 2 (2nd Milestone Deliverables and Criteria).
- 6.2.3 In the event that the Judging Panel determines in its sole discretion that a Solver's vaccine candidate has not met the criteria set out in Appendix 2 (2nd Milestone Deliverables and Criteria), the Solver will be allowed to submit a new or updated version of the 2nd Milestone Deliverables for another assessment in accordance with the process described above. **Solvers shall only be entitled to resubmit 2nd Milestone Deliverables once in accordance with this section up until the Phase 2 Closing Date (as described in Section 6.1.3).**

## 6.3 Selection of Solvers and payment of Milestone Payment 2

- 6.3.1 Solvers who either (a) submit 2nd Milestone Deliverables which are subsequently determined by the Judging Panel to meet or exceed the criteria set out in Appendix 2 (2nd Milestone Deliverables and Criteria) or (b) wish to proceed directly to Phase 3 without submitting 2nd Milestone Deliverables (and without therefore being eligible for Milestone Payment 2) as further described in Section 6.3.6, will in each case be entitled to progress to Phase 3 (the Final Phase). In order to be eligible to receive an available Milestone 2 Payment and/or to progress to Phase 3, academic or purely research organisations will need to provide evidence of support and commitment from a commercial organisation, as set out in Section 2.



- 6.3.2 The first 4 Solvers out of all eligible Solvers who submit 2nd Milestone Deliverables which are subsequently determined by the Judging Panel to meet or exceed the criteria set out in Appendix 2 (2nd Milestone Deliverables and Criteria), will receive Milestone Payment 2 (as defined below). Eligibility to receive Milestone Payment 2 in accordance with this section will be determined based on the date and time at which the Solver's online submission or email of the final eligible 2nd Milestone Deliverables was received by GALVmed. Proof of sending or submitting the 2nd Milestone Deliverables will not necessarily be deemed to be proof of receipt. GALVmed will inform all participating Solvers once all available Milestone Payments 2 have been awarded.
- 6.3.3 Following receipt of notice by GALVmed, in accordance with section 6.2.2, that a Solver's 2nd Milestone Deliverables has been successful, the Solver must notify GALVmed within 30 days if it agrees to progress to Phase 3.
- 6.3.4 Subject to section 6.3.6, in the event that the Judging Panel determines that no Solvers have submitted, by the Phase 2 Closing Date (as described in Section 6.1.3), 2nd Milestone Deliverables which meet or exceed the criteria set out in Appendix 2 (2nd Milestone Deliverables and Criteria), no Solvers may be selected to progress to the next Phase and receive Milestone Payment 2 and GALVmed shall be entitled to cancel the Competition at its sole discretion.
- 6.3.5 Milestone Payment 2 is a one-off payment of one million US dollars (\$1,000,000). In the event that a Solver has submitted multiple eligible Applications to the Competition in accordance with Section 2.1 which were successful as described in the Rules above and as a result such Solver submits multiple 2nd Milestone Deliverables as part of separate entries for Phase 2 – such Solver may be eligible to receive a separate Milestone Payment 2 for **a maximum of two sets of 2nd Milestone Deliverables** which are selected by the Judging Panel in accordance with this section, provided that the vaccine concepts are based on the use of sufficiently different concepts and/or technologies as determined by the Judging Panel in its sole discretion as described in Section 2.1above.
- 6.3.6 In the event that any Solver either does not wish to share its 2nd Milestone Deliverables with GALVmed (for example due to concerns regarding confidentiality) or having had its Application accepted as part of Phase 1 such Solver desires to proceed directly to Phase 3 for any other reason, in either case such Solver shall be entitled to notify GALVmed that the Solver has either successfully completed Phase 2 but does not wish to share its 2nd Milestone Deliverables with GALVmed or wishes to proceed directly to Phase 3 for any other reason. In such situation, the Solver **shall be not be eligible to receive Milestone Payment 2** but shall be entitled at GALVmed's discretion to proceed directly to Phase 3.

#### 6.4 [Efficacy Study Facility Funding](#)

- 6.4.1 [During Phase 2 of the Competition, Solvers have the option, but shall not be obliged, to submit an application \(the "Efficacy Study Facility Funding Application"\) for financial support in the form of an Efficacy Study Facility](#)

Payment (as defined in Section 6.4.13) in order to conduct the efficacy challenge study required as part of the 2nd Milestone Deliverables specified in paragraph 5 of Appendix 2 (the "Efficacy Study").

- 6.4.2 Efficacy Study Facility Funding Applications can be made at any time from August 9th 2021 up until the earlier of: (a) August 31st 2023; and (b) the date on which the third Efficacy Study Facility Funding Payment is awarded to a Solver. Efficacy Study Facility Funding Applications submitted after such date will not be considered for the grant of an Efficacy Study Payment.
- 6.4.3 An Efficacy Study Facility Funding Application may be submitted by any Solver that has progressed to Phase 2 of the Competition, including:
- (a) any Solver that requires financial support to conduct the Efficacy Study;
  - (b) any Solver that has already attempted an Efficacy Study which has not produced the data specified in paragraph 5 of Appendix 2 but such Solver would wish to conduct another Efficacy Study; and
  - (c) any Solver that has withdrawn from the Competition in accordance with Section 8.6 but would wish to recommence its participation in the Competition.
- 6.4.4 Efficacy Study Facility Funding Applications should be submitted to GALVmed online via the website located at [www.brucellosisvaccine.org](http://www.brucellosisvaccine.org) (or such other website as may be notified by GALVmed) using the application process set out on that website or via email to [brucellosis@galvmed.org](mailto:brucellosis@galvmed.org) (or such other email address as may be notified by GALVmed). Efficacy Study Facility Funding Applications must include all information and evidence set out in Appendix 6 .
- 6.4.5 An Efficacy Study Facility Funding Application shall only be considered in respect of a proposed Efficacy Study which is to be conducted at a BSL3 facility which complies with the requirements in Section 8.2.1 (the "Efficacy Study Facility").
- 6.4.6 The proposed start date of the Efficacy Study as set out in the Efficacy Study Facility Funding Application must be a date no later than twelve (12) months after the deadline for GALVmed to issue its response in accordance with Section 6.4.8 and in any event no later than [January 31st 2024]. If following submission of the Efficacy Study Facility Funding Application, the Efficacy Study Facility no longer has availability to commence the Efficacy Study on such proposed start date, the Solver shall use reasonable endeavours to secure the next earliest start date at the Efficacy Study Facility. GALVmed and the Solver shall discuss in good faith whether such later start date for the Efficacy Study is reasonable or not, but GALVmed shall retain sole discretion whether to issue the Efficacy Study Facility Funding in those circumstances.
- 6.4.7 On receipt of each eligible Efficacy Study Facility Funding Application from a Solver which complies with, and is submitted in accordance with, these Rules, the Judging Panel will evaluate and assess it to determine, in its sole discretion,

whether the application has met the criteria set out in Section 6.4 and Appendix 6 (Efficacy Study Application Requirements).

- 6.4.8 Following completion of the Judging Panel's evaluation and assessment of each Efficacy Study Facility Funding Application as described above, GALVmed will notify the applicable Solver whether it has succeeded or failed in its application for an Efficacy Study Facility Payment:
- (a) no later than December 31st 2021 for Efficacy Study Facility Funding Applications submitted on or prior to September 17th 2021;
  - (b) no later than April 1st 2022 for Efficacy Study Facility Funding Applications submitted after September 17th 2021 but prior to January 1st 2022; and
  - (c) no later than ninety (90) days after the date of the Solver's submission for any Efficacy Study Facility Funding Applications submitted on or after January 1st 2022.
- 6.4.9 The first three (3) Solvers out of all eligible Solvers who submit an Efficacy Study Facility Funding Application which is subsequently determined by the Judging Panel (in their sole discretion) to meet the criteria set out in Section 6.4 and Appendix 6 (Efficacy Study Facility Funding Application Requirements), will receive an Efficacy Study Facility Payment (as defined below). Eligibility to receive an Efficacy Study Facility Payment in accordance with this Section will be determined based on the date and time at which the Solver's online submission or email of the Efficacy Study Facility Funding Application was received by GALVmed. Proof of sending or submitting the Efficacy Study Facility Funding Application will not necessarily be deemed to be proof of receipt.
- 6.4.10 A maximum of three (3) Efficacy Study Payments in total may be issued and no Solver may receive more than one Efficacy Study Facility Payment (irrespective of how many Efficacy Study Applications that Solver has submitted).
- 6.4.11 There is no minimum number of Solvers who may be issued an Efficacy Study Facility Payment. Therefore, in the event that the Judging Panel determines that no Efficacy Study Facility Funding Applications sufficiently satisfy the evaluation criteria described above, no Solvers may be selected to receive an Efficacy Study Facility Payment.
- 6.4.12 GALVmed shall notify all Solvers of each decision by the Judging Panel to issue an Efficacy Study Facility Payment. Such notification shall also state how many of the up to three (3) Efficacy Study Facility Payments have been issued to date.
- 6.4.13 The Efficacy Study Facility Payment is a one-off payment of up to three hundred and fifty thousand US dollars (\$350,000), but in any event no more than the actual cost of conducting the Efficacy Study at the Efficacy Study Facility. The Efficacy Study Facility Payment will be paid by or on behalf of GALVmed directly to the Efficacy Study Facility and, for the avoidance of doubt, will not be paid to the Solver. If the budget for the Efficacy Study exceeds three hundred and fifty thousand US dollars (\$350,000), any shortfall will need to be met by the Solver.

- 6.4.14 The Efficacy Study Facility Payment may only be used to conduct the Efficacy Study and no portion of such payment may be allocated towards other work that may be conducted by or on behalf of the Solver at the Efficacy Study Facility.
- 6.4.15 In the event that aspects of a Solver's proposed Efficacy Study are to be conducted at one or more third party facilities other than the Efficacy Study Facility, the Solver may request that portion(s) of the Efficacy Study Facility Payment be paid to such other facilities. The Judging Panel will decide whether to satisfy such request at its sole discretion. The Efficacy Study Facility Payment shall in any event not be greater than as set out in Section 6.4.13.
- 6.4.16 A Solver that has been issued an Efficacy Study Facility Payment shall, as soon as reasonably possible following completion of the Efficacy Study or its early termination for any reason, submit the data obtained from the Efficacy Study, to GALVmed in accordance with Section 6.1.5. The data obtained from the Efficacy Study shall be submitted to GALVmed irrespective of whether the study was successful or not. Notwithstanding Section 6.3, a Solver that has received an Efficacy Study Facility Payment **shall not be eligible to receive Milestone Payment 2.**
- 6.4.17 In the event that the Efficacy Study of a Solver that has been awarded an Efficacy Study Facility Payment is not commenced within the timeframe specified in the Efficacy Study Facility Funding Application or any later date which may be agreed by the Solver and GALVmed in accordance with Section 6.4.6, GALVmed reserves the right to request a refund of the Efficacy Study Facility Payment from the Efficacy Study Facility and the Solver shall use all reasonable endeavours to assist GALVmed in obtaining such refund.
- 6.4.18 Each Solver shall conduct the Efficacy Study entirely at its own risk and the issuance of an Efficacy Study Facility Payment shall not constitute an endorsement or approval by GALVmed of the proposed Efficacy Study protocol or the choice of Efficacy Study Facility. Neither GALVmed, nor any of the AgResults Entities, nor the members of the Technical Committee and Judging Panel, shall have any liability to the Solver, the Efficacy Study Facility or any third party, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, for any loss, including without limitation any/all loss of profits, loss of business, development costs, depletion of goodwill and similar losses, costs, proceedings, damages and/or expenses, in each case whether direct or indirect or consequential, arising in connection with or pursuant to an Efficacy Study and/or the preparation and submission of any Efficacy Study Facility Funding Application.

## **7 Phase 3: The Final Phase**

### **7.1 Phase 3 Requirements and Structure**

- 7.1.1 Once each applicable Solver has been selected to proceed to Phase 3 and has confirmed that it has agreed to participate in Phase 3 as described in section 6.3, that Solver may proceed to Phase 3.

- 7.1.2 As part of Phase 3, Solvers will be required to take their vaccine candidates from their 2nd Milestone Deliverables to a registered product. The registered product must be awarded a marketing authorization ("MA") by the competent regulatory authority (as described in Section 7.1.3), which permits the product to be freely placed on the market in the applicable country subject to local laws. The Solver must follow the guidelines set forth by the World Organization for Animal Health (the "OIE") and the registration will be subject to the requirements set out below.
- 7.1.2.1 Subject to Section 7.1.2.2, Solvers must notify GALVmed of the date of submission to the relevant —competent authority for an MA immediately upon such submission. Any such notification to GALVmed by the Solver must also include a reasonable assessment by the Solver, using its reasonable professional judgment, of the probability of the MA, if granted, meeting the Minimum Viable Product requirements set out in Appendix 3 (MVP Requirements).
- 7.1.2.2 For any submission within the USA, the notification to GALVmed referred to in section ~~7.1.2.1~~ above must be made: (i) on application for the US Veterinary Biological Product License (APHIS form 2003) and (ii) on submission of final data for authorisation.
- 7.1.3 For the purposes of Phase 3, the registration of the vaccine must be in a country which is either a current member of the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products ("**VICH Country**") (which includes for the avoidance of doubt members of the EU, Japan and USA) or an AgResults donor country (i.e. UK, Canada, Australia, and USA).
- 7.1.4 GALVmed may at its sole discretion require any such Solvers to provide GALVmed with a copy of the dossier submitted in support of the applicable registration (the dossier must include the regulatory questions and answers).
- 7.1.5 Following commencement of Phase 3 for each Solver, the Solver agrees to provide GALVmed with a report every 6 months setting out details of the Solver's progress towards completion of Phase 3. The report should be substantially based on the template report form set out in Appendix 5 (Template Report Form).
- 7.1.6 The Solver's submission must be compliant with all applicable laws, including in relation to the development of immunological veterinary medicinal products in food-producing animals, and must satisfy any applicable requirements in relation to minimum residue limits.
- 7.1.7 Solvers must notify GALVmed immediately upon the successful grant of an MA, and with such notification provide sufficient evidence to GALVmed to enable GALVmed to verify that the MA has been granted. The date of the grant of the MA is the relevant date for the purposes of determining the date upon which the MA was granted. The deadline for submission of such notification is ~~10 years following the Application Start Date, i.e. [November 18th 2026]~~ May 18th 2028 ("**Final Phase Closing Date**").

- 7.1.8 Notice of a grant of an MA as described above received by GALVmed after the Final Phase Closing Date (i.e. ~~November~~ May 18th, ~~2026~~2028) will not be eligible.
- 7.1.9 Solvers are responsible for complying with all legal and regulatory obligations of MA holders including any pharmacovigilance requirements.
- 7.1.10 Solvers are responsible for paying any/all costs and expenses for and associated with any regulatory filings and registrations (including but not limited to: applications, variations, renewals and regulatory inspections).

## 7.2 Evaluation of Registrations

- 7.2.1 On receipt of notice of the successful grant of an MA as described above, the Judging Panel will verify whether the MA meets the requirements of section 7.1.2 and will evaluate and assess the registered vaccine to determine in its sole discretion whether it meets the Minimum Viable Product ("MVP") requirements set out in Appendix 3 (MVP Requirements).
- 7.2.2 In addition to the assessment described in section 7.2.1, the Judging Panel will also evaluate and assess the registered vaccine to determine in its sole discretion whether it meets any of the 4 Best in Class requirements set out in Appendix 4 (Best in Class requirements).
- 7.2.3 GALVmed will notify the applicable Solvers of the Judging Panel's decisions pursuant to sections 7.2.1 and 7.2.2 no later than 90 days after receipt of notice of the successful grant of an MA as described above.

## 7.3 Payment of the Grand Prize and Best in Class Prize

- 7.3.1 The first Solver to be granted an MA for a vaccine which is determined by the Judging Panel in its sole discretion to meet the MVP requirements set out above shall be awarded the Grand Prize (as defined below) provided that the Solver notifies GALVmed of the grant of the MA before the Final Phase Closing Date (i.e. ~~November~~ May 18th ~~2026~~2028) in accordance with the provisions of Section 7.1.7 above.
- 7.3.2 The first Solver to be granted an MA for a vaccine which is determined by the Judging Panel to meet the MVP requirements set out in Appendix 3 (MVP Requirements) and at least one of the 4 Best in Class requirements set out in Appendix 4 (Best in Class requirements) shall be awarded the Best in Class Prize (as defined below) provided that the Solver notifies GALVmed of the grant of the MA before the Final Phase Closing Date (i.e. ~~November~~ May 18th, ~~2026~~2028) in accordance with the provisions of Section 7.1.7 above.
- 7.3.3 In the event that the Solver awarded the Grand Prize is not also awarded the Best in Class Prize, the other Solvers shall be entitled, for up to 1 year following the award of the Grand Prize (irrespective of whether the Final Phase Closing Date (i.e. ~~November~~ May 18th, ~~2026~~2028) has been reached), to submit evidence of

the grant of an MA for a vaccine which meets both the MVP requirements set out above and at least one of the Best in Class requirements set out above, and therefore be entitled to win the Best in Class Prize.

- 7.3.4 The Grand Prize is a one-off payment of twenty million US dollars (\$20,000,000).
- 7.3.5 The Best in Class Prize is a one-off payment of five million US dollars (\$5,000,000).
- 7.3.6 In the event that by the Final Phase Closing Date (i.e. ~~November~~ May 18th, ~~2026~~ 2028), the Judging Panel determines that no Solvers have successfully been granted an MA for a vaccine which meet both the MVP requirements and at least one of the Best in Class requirements as described above, no Solvers will be awarded the Grand Prize or the Best in Class Prize and GALVmed shall be entitled to close the Competition at its sole discretion.

## **8 Solver obligations and warranties**

- 8.1 In these Rules, Milestone Payment 1 and Milestone Payment 2 shall collectively be referred to as "**Milestone Payments**" and The Grand Prize and The Best in Class Prize shall collectively be referred to as "**Prizes**".
- 8.2 Solvers agree to at all times whilst participating in the Competition:
  - 8.2.1 comply with all applicable laws, statutes, regulations, codes, standards, guidelines, protocols (including without limitation the World Health Organization and other applicable biosafety protocols), from time to time in force including without limitation any laws related to medical or pharmaceutical research and testing, animal testing, safety and security of its personnel, and anti-bribery and corruption laws;
    - 8.2.1.1 Subject to section 8.2.1.2 target animal studies must be run in approved BSL3 facilities
    - 8.2.1.2 The only exception to the requirement in section 8.2.1.1 shall be where a Solver provides evidence from the relevant competent authority(ies) that such studies can be conducted in compliance with section 8.2.1 above under lower biosecurity containment conditions due to the nature of the materials being used. Notwithstanding the foregoing, all target animal challenge studies must still be conducted in approved BSL3 facilities.
  - 8.2.2 not do anything which may damage the reputation or integrity of GALVmed, the AgResults Entities or the Competition or bring them into disrepute;
  - 8.2.3 not undertake in any activities or behavior which is unethical, fraudulent, or otherwise inappropriate;
  - 8.2.4 use reasonable care and skill in the performance of its obligations and participation in the Competition in each case in accordance with good industry practice; and

- 8.2.5 conduct all experiments rigorously and safely, with consideration of animal welfare.
- 8.3 Solvers warrant that:
- 8.3.1 any/all information provided during all Phases of the Competitions will be accurate and true; and
- 8.3.2 in participating in the Competition and providing information, data and other materials to GALVmed and the AgResults Entities, it will not infringe any third party rights (including without limitation intellectual property rights and regulatory data protection rights).
- 8.4 Consistent with UN Security Council Resolutions relating to terrorism, including UNSC Resolution 1373 (2001) and 1267 (1999) and related resolutions, GALVmed and the AgResults Entities are firmly committed to the international fight against terrorism, and in particular, against the financing of terrorism. In relation to the foregoing, Solvers warrant that:
- 8.4.1 neither they nor any of their personnel have been identified on any Anti-Money Laundering/Combating the Financing of Terrorists sanctions lists monitored by the World Bank Group, including but not limited to the United Nations 1267 sanctions list, the United States Executive Order 13224 sanctions list, and the United Kingdom terrorist sanctions list; and
- 8.4.2 no Milestone Payments or Prizes will be used, directly or indirectly, to provide support to or assist individuals or entities associated with terrorism.
- 8.5 If at any time GALVmed discovers that a Solver or its Application is ineligible, or is otherwise in breach of the Rules (including without limitation, if GALVmed determines that the applicable Solver has acted fraudulently in any manner), Solvers will be given the opportunity to remedy the breach (if remediable, **which shall not be the case in the event of fraud**) within 30 days, and if not remedied or remediable, GALVmed reserves the right to:
- 8.5.1 withhold provision of any Milestone Payments or Prizes;
- 8.5.2 require the Solver to repay to the applicable donors any Milestone Payments or Prizes awarded to the Solver;
- 8.5.3 -disqualify the applicable Solver from participation in the Competition and/or
- 8.5.4 select an alternative Solver using the same processes referred to in these Rules, in each case without prejudice to any legal rights and/or remedies GALVmed may have.
- 8.6 Solvers may, by providing GALVmed with written notice, withdraw from the Competition at any time without giving a reason. Any Solver who withdraws from the Competition shall no longer be eligible to receive any Milestone Payments and/or Prizes.



## **9 Independent Evaluation**

- 9.1 Abt Associates, Inc. ("**Abt**") have been appointed by the AgResults Entities for the Competition to independently evaluate the effectiveness of the Competition as a means of achieving the purpose described in Section 1.2 above.
- 9.2 Abt may request Solvers to share information with Abt and/or participate in interviews regarding that Solver's participation in the Competition. However, Solvers are under no obligation to share any such information and/or participate in any such interviews and in each case may do so at their sole discretion and subject to the agreement of confidentiality obligations between Abt and the Solver as reasonably required by the Solver.

## **10 Confidentiality**

- 10.1 For the purposes of these Rules and subject to section 10.2, "**Confidential Material**" shall mean:

10.1.1 any confidential information including without limitation forecasts, analyses, evaluations, research, clinical trials, business information, financial information, commercial strategies, business plans, production processes, manufacturing plans, customer lists, marketing plans, or other information of a confidential nature whether in verbal, written, electronic or in any other form;

10.1.2 any prototypes, compounds, components or other physical items of a confidential nature; or

10.1.3 any analyses, compilations, studies, minutes of meetings, documents or other content in any form that contain or are derived from any such information and/or materials as described above;

in each case disclosed or made available by GALVmed, the AgResults Entities, the Judging Panel or a Solver on or after the date of signature of these Rules.

- 10.2 Confidential Material shall not include any information or materials which:

10.2.1 is or becomes public knowledge through no improper conduct on the part of the receiving party;

10.2.2 is already lawfully possessed by the receiving party prior to receiving it from the disclosing party; and/or

10.2.3 is obtained subsequently by the receiving party from a third party without any obligations of confidentiality and such third party is in lawful possession of such information and/or materials and is not in violation of any contractual or legal obligation to maintain the confidentiality of such information and/or materials.

- 10.3 Subject to the provisions of this section, the receiving party shall treat all Confidential Material as secret and confidential.

- 10.4 The receiving party shall not use, copy or disclose to any third party any Confidential Material except as expressly set out in this section.

- 10.5 The receiving party may:
- 10.5.1 use Confidential Material solely for the purpose of applying to, participating in and/or administering the Competition (as applicable);
  - 10.5.2 disclose any part of the Confidential Material solely to the extent that it is legally required to do so pursuant to a request from an applicable regulatory authority or an order of a court of competent jurisdiction provided that the receiving party shall use its best endeavors to limit such disclosure and provide the disclosing party with an opportunity to make representations to the relevant court.
- 10.6 Solvers acknowledge and agree that GALVmed may share Confidential Material provided by Solvers with the AgResults Entities and with the Judging Panel and individuals appointed as the Technical Committee for the Competition in each case on a need-to-know basis solely for the purpose of administering and managing the Competition in accordance with the Rules.
- 10.7 All documents, files or other items containing any Confidential Material shall remain the absolute property of the disclosing party.
- 10.8 The receiving party shall at the request of the disclosing party return to the disclosing party forthwith all documents, files or other items containing any Confidential Material in the possession or control of the receiving party, except that GALVmed and the AgResults Entities shall be entitled to retain copies of Solvers' Confidential Material disclosed to them as may be necessary for internal administrative and audit purposes related to the Competition and provided that any such Confidential Information shall at all times remain subject to the confidentiality obligations contained in these Rules.
- 10.9 For the avoidance of doubt, nothing in the Rules shall require GALVmed to disclose any Confidential Material to the Solver or enter into any further agreement in respect of the Confidential Material and/or the Competition with the Solvers.
- 10.10 Except as expressly set forth in the Rules, neither GALVmed nor the Solvers grant by implication, estoppel or otherwise, any right, title, license or interest in any intellectual property right.
- 10.11 GALVmed and the Solver shall promptly notify the other if it becomes aware of any unauthorized disclosure or use of any of the Confidential Material of the other party.
- 10.12 GALVmed and the Solver acknowledge that damages alone would not be an adequate remedy for any breach of the confidentiality obligations in the Rules. Accordingly, without prejudice to any other rights or remedies that a party may have, each party agrees that the other (and the AgResults Entities) shall be entitled to equitable relief, including injunctions and orders for specific performance, in the event of any breach of the confidentiality obligations in the Rules, in addition to all other remedies available at law or in equity.
- 10.13 Notwithstanding any provision to the contrary in the Rules, the confidentiality obligations in the Rules shall continue in force for a period of 10 years following the closing or cancellation of the Competition.

## **11 Intellectual Property Rights**

- 11.1 Solvers will retain ownership of any/all discoveries, content, submissions, data, vaccines and other material they develop and/or submit as part of their application to and participation in the Competition (together with all intellectual property rights and regulatory data protection rights subsisting therein).
- 11.2 Solvers grant GALVmed, its agents and the AgResults Entities, a non-exclusive, worldwide, irrevocable, perpetual license to use any such content, submissions and other material solely for the purposes of administering the Competition. For the avoidance of doubt any such content, submissions and other material will only be used to the extent necessary for the purpose of administering the Competition and, as described in Section 11.1, Solvers will retain ownership of the intellectual property rights in any such content, submissions, and other material.
- 11.3 GALVmed gives no warranty or representation, express or implied: (i) as to the truth, accuracy, efficacy, completeness, capabilities or safety of any information or materials supplied to Solvers; or (ii) that any information or materials supplied to Solvers will not infringe any third party rights (including without limitation intellectual property rights).
- 11.4 GALVmed grants the Solver, subject to section 14.2, a non-exclusive, non-transferable, royalty-free license for the duration of its participation in the Competition to use the GALVmed and Competition branding and trade marks as provided and/or made available to the Solver ("**Branding**") for the purpose of participating in the Competition, in all cases in accordance with GALVmed's brand guidelines (as provided to the Solver) as they may be amended and/or updated by GALVmed from time to time and notified to Solvers.
- 11.5 The Solver acknowledges that that it will not gain any right, title or interest in the Branding or associated goodwill, which shall vest automatically in GALVmed or the AgResults Entities as applicable.

## **12 Indemnity**

- 12.1 The Solver shall indemnify and hold GALVmed, the AgResults Entities and the members of the Technical Committee and Judging Panel, harmless from all claims (including without limitation product liability claims) and all direct, indirect or consequential liabilities, costs, proceedings, damages and expenses (including legal and other professional fees and expenses) awarded against, or incurred or paid by them, as a result of or in connection with:
- 12.1.1 any alleged or actual infringement of any third party's rights (including without limitation intellectual property rights or other rights) arising out of the Solver's participation in the Competition;
- 12.1.2 any breach or negligent performance by the Solver of any provision of the Rules; and/or
- 12.1.3 the development or use of products developed in connection with this Competition (including without limitation any adverse effects of a vaccine to

animals, risk to persons handling and administering the vaccine, and/or consumers of food of animal origin).

### **13 Limitation of Liability**

- 13.1 Nothing in the Rules shall limit or exclude GALVmed's liability for (a) death or personal injury caused by its negligence, (b) fraud or fraudulent misrepresentation; or (c) any other liability which cannot be limited or excluded by applicable law.
- 13.2 Subject to section 13.1, the Solver acknowledges that it participates in the Competition and puts any vaccine on the market entirely at its own risk and neither GALVmed, nor any of the AgResults Entities, nor the members of the Technical Committee and Judging Panel, shall have any liability to any Solver, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, for any loss, including without limitation any/all loss of profits, loss of business, development costs, depletion of goodwill and similar losses, costs, proceedings, damages and/or expenses, in each case whether direct or indirect or consequential, arising under or in connection with the Rules or the Solver's application to and/or participation in the Competition.

### **14 Publicity and announcements**

- 14.1 Solvers may be requested to take part in publicity relating to the Competition as agreed between GALVmed and the Solver from time to time. Unless required by applicable law or regulations, and in each case subject to the confidentiality obligations contained in the Rules, any publication of a particular Solver's name in relation to the Competition shall be subject to the Solver's prior consent.
- 14.2 The Solver shall not make, or permit any person to make, any public announcement, or comment upon, or originate any publicity, or otherwise provide any information to any third party (other than its legal advisors) concerning the Competition or the Rules without the prior written consent of GALVmed, except as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction.

### **15 Dispute Resolution**

- 15.1 If a dispute arises out of or in connection with the Rules or the Solver's participation in the Competition (including without limitation the payment or non-payment of any Milestone Payment or Prize) (a "**Dispute**"), then the following procedure shall be followed:
- 15.1.1 the Solver shall give to GALVmed written notice of the Dispute, setting out its nature and full particulars (a "**Dispute Notice**"), together with any relevant supporting documents.
- 15.1.2 On service of a Dispute Notice, the Project Manager of GALVmed and an individual of equivalent seniority at the Solver shall attempt in good faith to resolve the Dispute.
- 15.1.3 If the Dispute is not resolved for any reason pursuant to section 15.1.2 within 30 days of service of the Dispute Notice, the Dispute shall be referred to the CEO of

GALVmed and an individual of equivalent seniority at the Solver who shall attempt in good faith to resolve it.

- 15.1.4 If the Dispute is not resolved for any reason pursuant to section 15.1.3 within 30 days of the Dispute being referred, the parties will attempt to settle it by mediation in accordance with the CEDR Model Mediation Procedure. Unless otherwise agreed between the parties, the mediator shall be nominated by CEDR Solve. To initiate the mediation, a party must serve notice in writing (an "**ADR notice**") to the other party to the Dispute, requesting a mediation. A copy of the ADR notice should be sent to CEDR Solve. The mediation will start not later than 30 days after the date of the ADR notice.
- 15.2 Neither the Solver nor GALVmed may commence any court proceedings under or in relation to the whole or part of a Dispute until 90 days after service of an ADR notice, provided that the right to issue proceedings is not prejudiced by a delay.

## **16 General**

- 16.1 GALVmed shall be entitled to amend the Rules at any time on notice to the Solvers. In the event of any such amendments, Solvers will be provided with as much notice as is reasonably practicable in the circumstances and any such amendments shall apply equally to all Solvers who are then participating in the Competition but will not affect any submissions to the Competition made prior to the amendment.
- 16.2 Solvers acknowledge and agree that each of the AgResults Entities is a third party beneficiary of the obligations owed by Solvers under the Rules and has the right to enforce any applicable terms directly against the applicable Solver. Other than as expressly stated in the Rules, a person who is not a party to the Rules has no right to enforce any term in the Rules.
- 16.3 On expiry or termination of the Rules for any reason, the following sections shall remain in force: section 10 (Confidentiality), section 12 (Indemnity), and section 13 (Limitation of Liability), together with any other sections the survival of which is implied in order to interpret the Rules.
- 16.4 GALVmed shall at any time be entitled to postpone and/or cancel the Competition entirely in the event it is no longer able to administer the Competition due to circumstances outside its control.
- 16.5 Payments of all Milestone Payments and Prizes shall be in US Dollars only and to a Solver's bank account nominated by the applicable Solver in writing.
- 16.6 Solvers are responsible for all expenses not expressly stated in the Rules as being included as part of a Milestone Payment or Prize. Taxes on the value of any Milestone Payment and/or Prize are the Solvers' sole responsibility.
- 16.7 Under no circumstances shall any interest be payable as a result of the late or delayed payment of any Milestone Payment and/or Prize for any reason. Notwithstanding any other provision in the Rules, GALVmed may, at sole discretion, delay payment of any Milestone Payment and/or Prize pending the resolution of any dispute with a Solver, or in the event of any allegations of fraud or any investigation related to the Competition.

- 16.8 Other than as expressly set out herein, the Solver shall not be entitled to assign or otherwise transfer its rights and/or obligations under the Rules. GALVmed may at any time assign, subcontract, delegate, novate or deal in any other manner with any or all of its rights and obligations under these Rules.
- 16.9 Incomplete, illegible, corrupted applications or submissions, or those which are otherwise not in accordance with the Rules will not be valid or eligible. GALVmed accepts no responsibility for failure to receive an application or any submissions where such failure is due to circumstances outside GALVmed's control.
- 16.10 No alternative to a Milestone Payment or Prize will be offered save in the event of unforeseen circumstances.
- 16.11 GALVmed, its agents and the AgResults Entities will only use personal information supplied by Solvers for the purposes of administering the Competition, unless consent is received to use such information for any other purpose.
- 16.12 The name(s) of the winning Solvers will be made available on request to those sending a stamped, self-addressed envelope to GALVmed at the contact details above.
- 16.13 Any failure or delay by GALVmed to exercise any rights or powers under the Rules shall not be deemed to be a waiver of those or any other rights, nor will any single or partial exercise of them preclude any further exercise, unless expressly so agreed in writing by GALVmed.
- 16.14 The Rules (and any non-contractual disputes/claims which arise out of or in connection with them) will be governed by English law and Solvers submit to the exclusive jurisdiction of the English courts.

**SIGNED** by a signatory, duly authorized  
on behalf of Solver [Enter Full Organization Name Below]

.....

*Signature*.....

*Print Name*.....

*Date*.....

**Appendix 1 – Application Criteria**

1. Scientific soundness and plausibility of the presented concept.
2. Suitability of manufacturing capabilities (either those of the Solver or the proposed third party partner as per Section 2 of the Rules).
3. Suitability of the relevant animal research facilities (either those of the Solver or the proposed third party partner as per Section 2 of the Rules).

## Appendix 2 – 2nd Milestone Deliverables

1. All target animal studies must be conducted under controlled conditions in registered BSL3 facilities or such other approved facilities further to sections 8.2.1.1 and 8.2.1.2, in all cases proof of this must be provided.
2. Detailed protocols (in line with the OIE Guidelines, and principles of Good Laboratory Practice (GLP) or Good Clinical Practice (GCP)) shall be prepared for each study stating the proposed experimental approach. Reports shall be prepared which include all the results and any deviations from the planned protocol.
3. R&D batches of Candidate vaccine can be used for the proposed target animal studies run in registered BSL3 facilities or such other approved facilities further to sections 8.2.1.1 and 8.2.1.2. A Certificate of Analysis for vaccine batches shall be provided.
4. Demonstration of proof of principle of **Safety** of the candidate vaccine in pregnant sheep or goats when administered in all stages of gestation such that;
  - No more than 5% of the vaccinated animals should abort due to the vaccine strain. Shedding of the vaccine strain should be monitored in ewes or does for two weeks post-partum.
  - Within 4 weeks post-partum, ewes/does and lambs/kids should be euthanized and colonization of the vaccine strain should be assessed in all pertinent organs (as defined by standard protocols). Any aborted material should also be evaluated for the presence of the vaccine strain.
5. Demonstration of proof of principle of **Efficacy\*** of the vaccine in pregnant sheep or goats against a *B. melitensis* challenge such that:
  - The vaccine demonstrates 80% or higher protection\*\* compared with unvaccinated animals in controlled trial conditions; in these trials the challenge dose should be stringent enough that at least 90% of unvaccinated challenged animals abort
  - Shedding of the vaccine strain and the challenge strain should be monitored in ewes/does for two weeks post-partum.
  - Within 4 weeks post-partum, ewes/does and lambs/kids should be euthanized and colonization of the vaccine strain and the challenge strain should be assessed in all pertinent organs (as defined by standard protocols). Any aborted material should also be evaluated for the presence of the vaccine and the challenge strain.
6. Preparation of Master Seed and test for purity (minimum 500 vials).
7. Demonstration that the method for production of the vaccine is defined and that sufficient progress is being made to scale up production for commercial use. Assays of the active ingredient for formulation and a potency release assay for finished product should be presented.

\*For efficacy, the data obtained for the vaccine candidate under evaluation may be compared with data for Rev1 as published in the scientific literature. As an example of such, Solvers are encouraged to refer to the following publication, [it being acknowledged that the study design set out therein, including study group size, is not the only valid way in which efficacy of the vaccine candidate may be demonstrated:](#)

Jean-Michel Verger, Maggy Grayon, Etienne Zundel, Patrick Lechopier and Veronique Olivier-Bernardin: Comparison of the efficacy of Brucella suis strain 2 and Brucella melitensis Rev. 1 live vaccines against a Brucella melitensis experimental infection in pregnant ewes. Vaccine. Vol. 13, No. 2, pp. 191-196, 1995

\*\*For all trial results, animals are considered to be protected when no abortion, no excretion of the challenge strain and no infection at slaughter (in carcasses) occurs.



### Appendix 3 – Minimum Viable Product "MVP" Requirements

<b>Species/Animal</b>	<ul style="list-style-type: none"> <li>• <i>B. melitensis</i> in sheep or goats, with a potential to add the second target animal species to the label later (small ruminant category)</li> </ul>
<b>Animal Safety</b>	<ul style="list-style-type: none"> <li>• <b>Safety in pregnant animals:</b> In all stages of gestation, no more than 5% of the vaccinated animals should abort due to the vaccine strain</li> <li>• <b>Shedding:</b> On par with or less than Rev1 in milk, aborted material, vaginal, and semen secretions</li> <li>• <b>Long-Term Persistence of the Vaccine Strain/Colonization:</b> For whole Brucella bacterium attenuated vaccines should be less than 2 months</li> <li>• <b>Adverse reactions:</b> Any adverse reactions should be compliant with applicable regulatory criteria and must be deemed acceptable by the Judging Panel</li> <li>• <b>Minimum Age of Vaccination:</b> 3 Months</li> <li>• If a live organism, demonstrate no reversion to virulence</li> </ul>
<b>Route of Administration</b>	<ul style="list-style-type: none"> <li>• Administration via ocular (palpebral), other mucosal, intramuscular, subcutaneous, or other suitable innovative route</li> </ul>
<b>Efficacy*</b>	<p><b>Efficacy*</b> of the vaccine in pregnant sheep or goats against a <i>B. melitensis</i> challenge such that:</p> <ul style="list-style-type: none"> <li>• The vaccine demonstrates 80% or higher protection** compared with unvaccinated animals in controlled trial conditions; in these trials the challenge dose should be stringent enough that at least 90% of unvaccinated challenged animals abort</li> </ul> <p>**For all trial results, animals are considered to be protected when no abortion, no excretion of the challenge strain and no infection at slaughter (in carcasses) occurs</p>
<b>Duration of Protection</b>	<ul style="list-style-type: none"> <li>• Single vaccination annually or duration of protection lasts for at least two gestations with a single vaccination.</li> </ul>
<b>Shelf Life</b>	<ul style="list-style-type: none"> <li>• No less than 18 months under controlled conditions</li> </ul>
<b>Cost</b>	<ul style="list-style-type: none"> <li>• Affordability for smallholder farmers, including a sufficiently low cost of manufacturing.</li> </ul>

\*For efficacy, the data obtained for the vaccine candidate under evaluation may be compared with data for Rev1 as published in the scientific literature. As an example of such, Solvers are encouraged to refer to the following publication, [it being acknowledged that the study design set out therein, including study group size, is not the only valid way in which efficacy of the vaccine candidate may be demonstrated:](#)

Jean-Michel Verger, Maggy Grayon, Etienne Zundel, Patrick Lechopier and Veronique Olivier-Bernardin:  
 Comparison of the efficacy of Brucella suis strain 2 and Brucella melitensis Rev. 1 live vaccines against a Brucella melitensis experimental infection in pregnant ewes. Vaccine. Vol. 13, No. 2, pp. 191-196, 1995

#### **Appendix 4 – Best in Class Requirements**

1. **Cross-species protection** - a multi-species vaccine with cross protection against both *B. melitensis* in small ruminants and *B. abortus* in cattle\*
2. **Providing maximum human and animal safety** – an efficacious vaccine meeting the MVP requirements and one that would offer an enhanced level of human and animal safety by demonstrating that the vaccine strain would no longer be able to replicate or have reduced pathogenic potential. This could be accomplished by vaccine approaches such as inactivated, a sub-unit, recombinant, DNA, non-replicating, vectored or similar approaches.
3. **Thermo-resistant formulation** – Stays effective after being kept at a minimum of 45 degrees centigrade for 3 weeks or more.
4. **Curative effect on infected animals** – boosts or redirects the immune response in such a manner as to facilitate clearing of the infection and/or reducing abortions or clinical signs in these animals at a statistically significant level.

\*Product performance for *B.abortus* in cattle should be on par with currently available commercial vaccines.

**Appendix 5 – Template Report Form**

**Solver Progress Report**

**Organization Name:** \_\_\_\_\_ **Report Date:** \_\_\_\_\_

**Contact Name:** \_\_\_\_\_ **Contact Email:** \_\_\_\_\_

**Project Progress Summary towards (check applicable milestone)**

Phase 2 Milestone  Phase 3 Milestone

<b>Key Project Steps</b>	<b>Description</b>	<b>Status (Achieved, On Track, Delayed)</b>

**Key Risks / Mitigation**

<b>Key Project Risk</b>	<b>Mitigation / Action</b>

**Additional Comments**

**Appendix 6 - Efficacy Study Facility Funding Application Requirements**

A valid Efficacy Study Facility Funding Application shall include all of the following:

1. Subject to paragraph 3 below, All data in support of the 2nd Milestone Deliverables (as set out in Appendix 2 Appendix-2), including any of the Solver's existing efficacy data but excluding data which will be generated as part of the proposed Efficacy Study which is the subject of the Efficacy Study Facility Funding Application.
2. Subject to paragraph 3 below, A study protocol for the proposed Efficacy Study which demonstrates the ability of the study to generate data which could satisfy the requirements specified in paragraph 5 of Appendix 2 (efficacy data).
3. The Efficacy Study shall be permitted to include some work to demonstrate the safety of the candidate vaccine. In which case the Solver will not be required to submit, as part of the Efficacy Study Facility Funding Application, data which satisfies those elements of the requirements specified in paragraph 4 of Appendix 2 (safety data), which the study protocol demonstrates the ability to generate; provided that (i) the application includes all safety data gathered to date by the Solver; and (ii) on balance, on the basis of the Solver's submission and any such data provided, as at the time of submission the application shows that the Efficacy Study is unlikely to fail due to safety issues.
4. A firm quote from an Efficacy Study Facility to conduct the Efficacy Study in accordance with the study protocol referred to above, including the proposed study timeline and detailed budget. The proposed start date of the Efficacy Study as set out in such firm quote shall comply with the requirements in Section 6.4.6.

For clarity, as part of the Efficacy Study Facility Funding Application, Solvers which are academic or purely research organisations will not need to provide evidence of support and commitment from a commercial organisation, as set out in Section 2 and Section 6.3.1.