Appendix F

Model term sheet for Framework Agreement

1. Parties:	One or more nongovernmental, grant-making organizations (such as a foundation) or governmental grant-making organizations (such as the U.S. Agency for International Development or the U.K. Department for International Development) (each, a **"Funder"**)[1] and one or more pharmaceutical or biotech companies[2] that will work within the Framework (as defined below) to develop eligible vaccine(s) (each, a **"Developer**").
2. Purpose:	Create a legally binding series of agreements[3] that guarantees the developer(s) of a [_____] vaccine[4] that meets the requirements set forth in the agreements a specific price for each qualified sale of the vaccine in certain designated developing countries (the **"Framework"**). The Framework Agreement will clearly state the goals and objectives of the Framework with regard to the target disease, the eligible countries and the affected populations.[5]
3. Benefits to Funder:	Fulfills the Funder's philanthropic mission (or a statutory or regulatory mandate, in the event Funder is a governmental organization) by giving Developers an economic incentive to (a) select and implement R&D projects that are likely to lead to vaccines developed specifically for diseases concentrated in developing countries, and (b) establish manufacturing capacity for production of such vaccines.
4. Benefits to Developers:	Establishes a specific price for all eligible sales of the vaccine in developing countries that allows the Designated Supplier (as defined below) to cover, over the term of the agreements, R&D costs as well as manufacturing costs and to make an acceptable return on its investment. The guaranteed price will be based on a per-patient dosing regimen to provide the required prophylactic benefit and will be paid on all eligible sales up to the maximum number specified in the Guarantee and Supply Agreement (the **"Maximum Guaranteed Amount"**). For example, if a course of 3 immunizations are required to provide the necessary immunity, the guaranteed price is $15 and the Maximum Guaranteed Amount is 200 million, then the Developer would receive the guaranteed price of $15 only upon an eligible sale of all three doses comprising the course of treatment. If the Developer's total eligible sales equal the Maximum Guaranteed Amount, 600 million doses, or 200 million courses of treatment, then the Developer would receive a total payment of $3 billion.[6]

Notes

1. The Framework Agreement and Guarantee Agreement term sheets were designed to accommodate a variety of Funders, despite the fact that there are substantial differences between governmental and nongovernmental organizations in areas such as funding capacity and ability to contractually commit to the Guarantee Agreement. We concluded that traditional commercial mechanisms for ensuring compliance, such as letters of credit or escrow arrangements, would be unattractive to potential Funders as they would result in increased transaction costs and unnecessarily tie up funds that could be made available for more immediate opportunities. Instead, we designed a bilateral contract structure, which would permit the Developer to pursue standard contract remedies, such as money damages and specific performance, if the Funders fail to satisfy their financial commitments.

2. The Framework and Guarantee term sheets were designed to allow participation by both pharmaceutical companies and biotechnology companies. We considered, but did not incorporate, an alternative funding system recommended by a few of the biotechnology companies interviewed that would provide for interim payments, upon the achievement of certain predetermined milestones, to create incentives for research and early-stage development activities and encourage venture capital investment in emerging companies committed to the Framework. We intend that intermediate incentives of this kind will be created by the commercial activities of Developers in the expectation of being remunerated through sales of vaccines under the Guarantee Agreement.

3. Initially, the Working Group considered establishing the Framework Agreement as a form of unilateral agreement. A unilateral agreement is an offer by one party, in this case the Funder, which only becomes a contract when it is accepted by the other party, the offeree or in this case the Developer. A unilateral agreement permits the offeror is withdraw its offer prior to acceptance, and what constitutes acceptance is not always clear, particularly in this context. We thought this risk might create too much uncertainty for the Developer and thereby dilute the effect of the commitment. The Framework Agreement as reflected in this term sheet would be bilateral agreement, which would be binding on the Funders as soon as one or more Developers sign on.

4. The Working Group initially intended that the Framework Agreement and Guarantee Agreement term sheets would be used for both late-stage and early-stage vaccine candidates. However, on further consideration, we decided that a form approach did not make sense for late-stage vaccine candidates, given the fact that specific Developers and Approved Vaccines had been identified for Rotavirus, and the recognition that each Developer had specific needs and objectives. Instead, the Working Group recommended that the Developers and the Funders directly negotiate long-term supply or other appropriate arrangements to ensure reliable, affordable supply to meet the long-term needs of Eligible Countries, while providing appropriate rewards for the vaccine developer.

5. Each Framework Agreement will establish a specific price for qualified sales of an Approved Vaccine, by supplementing the "base price" paid by a vaccine purchaser (such as UNICEF on behalf of the developing country) up to a certain fixed amount.

6. We concluded that the price guarantee should be for "per course of treatment" rather than "per dose." This approach provides incentives to ensure that all doses of multiple dose vaccines are administered, and encourages the development of vaccines requiring fewer doses where scientifically possible.

5. Principal Responsibilities of the Funder:	The Funder shall (a) upon satisfaction of the conditions precedent set forth in Section 7, enter into a Guarantee and Supply Agreement (in the form attached to the Framework Agreement) with one or more Designated Supplier(s) (as defined below),[7] (b) fund the operation of the Independent Adjudication Committee (as defined below) in accordance with budgeted amounts, (c) indemnify the members of the Committee for claims and losses arising out of the performance of their duties under the Framework Agreement and the Guarantee and Supply Agreement,[8] (d) retain the Contract Administrators (as defined below) to administer the Framework in accordance with budgeted amounts, (e) maintain in strict confidence any confidential business information submitted to it by the Developers, and (f) agree to be bound by decisions of the Committee acting within the scope of its authority.
6. Principal Responsibilities of Developers:	Each Developer shall (a) provide confidential reports to the Independent Adjudication Committee on the progress of its development efforts at the times specified by the Committee (it is contemplated that these reports would be high-level annual status reports at the outset and would increase in frequency and detail as the development efforts advance),[9] (b) provide such technical information as may be reasonably requested by the Committee in order to confirm that the conditions precedent set forth in Section 7 have been satisfied, and (c) agree to be bound by decisions of the Committee acting within the scope of its authority.
7. Conditions Precedent to Obligations of Funder:	It shall be a condition precedent to Funder's obligation to enter into and perform its obligations under the Guarantee and Supply Agreement that the vaccine meet (a) the technical specifications outlined in Section 8 below, and (b) the usability requirements outlined in Section 9 below.[10]
8. Technical Specifications:	For a vaccine to meet the technical specifications it must, subject to Section 10, satisfy the approval, safety and efficacy requirements set forth in Schedule A.
9. Usability Requirements:	For a vaccine to meet the usability requirements it must, subject to Section 10, satisfy the dosage, means of delivery, storage, shelf life and other requirements set forth in Schedule A.
10. Waiver of Conditions Precedent:	After the effective date of the Framework Agreement the Independent Adjudication Committee may (by a 2/3 vote of its members or at the direction of the Funder) waive or modify the technical specifications or usability requirements in a way that does not materially increase the cost of performance for a Developer. For purposes of illustrating the foregoing, if a specification called for 60% effectiveness, the Committee could, by a 2/3 vote of its members, reduce the requirement to 50% effectiveness, but could not increase it to 70% effectiveness under this provision.[11]

7. Until a vaccine is approved under the conditions set forth in Section 7 of the Framework Agreement term sheet, the Funder is only required to commit to the Framework Agreement, and fund the functions of the Independent Adjudication Committee. Once an Approved Vaccine is identified, the Developer has the right, and the Funder the obligation, to enter into the Guarantee Agreement with respect to that product.

8. Indemnification was deemed to be particularly important to attract qualified members to serve on the Independent Adjudication Committee. It is contemplated that this indemnification would be similar to that which is provided to officers and directors of corporations. Accordingly, the indemnification of the members of the Independent Adjudication Committee may exclude intentional misconduct or actions that are conducted in bad faith or for personal gain.

9. Developers may provide confidential information to the Independent Adjudication Committee in two circumstances. First, Developers would submit progress reports to the Independent Adjudication Committee during the term of the Framework Agreement. These reports will provide a way to evaluate the effectiveness of the mechanism during the research and early development periods. These reports, if not promising, may permit the Funder to withdraw from the Framework Agreement under Section 25 of the term sheet. Second, for those Developers seeking to participate at a later date, the Framework Agreement requires some evidence that the Developer has a technology or expertise with scientific promise for the development of an Approved Vaccine.

10. Although the Framework Agreement is designed to create an enforceable bilateral contract between the Developers and the Funders, the Funders would not be obligated to enter into the Guarantee Agreement until a product is tendered that meets certain minimum technical specifications, such as approval of both the product and its manufacturing process by a qualified regulatory body and certain safety, efficacy and use requirements.

11. Because there was concern that the Developer should be assured that the Funder could not change the rules of the game after the Framework Agreement was entered into, technical requirements cannot be changed to increase the burden of those requirements, unless there is a significant change in circumstances with respect to the disease that would significantly reduce the need for a vaccine or undermine the specifications, such as a dramatic decrease in disease prevalence, a significant change in disease transmission or progression or a major advancement in treatment. As noted below, these types of changes would be subject to judicial review. Technical requirements may be decreased, however, at the discretion of the Independent Adjudication Committee.

11. Testing and Acceptance:	The Developer shall submit the vaccine to the Independent Adjudication Committee for testing and acceptance. The Committee shall be responsible for making determinations with respect to whether a vaccine tendered by a Developer satisfies the conditions precedent set forth in Section 7, provided that the Independent Adjudication Committee shall have the right to delegate this responsibility to one or more third parties that it determines are qualified to make such determinations and are independent and unbiased, such as, for example, the World Health Organization's prequalification process.[12] Further, the Committee shall have the right to retain one or more consultants or rely on the actions of governmental or other third parties, such as the United States Food and Drug Administration, in making its determinations. In addition, the Committee shall have authority to grant waivers of, or make modifications to, the application of specific technical specifications or usability requirements as provided in Sections 10 and 22.
12. Designated Supplier:	If the Independent Adjudication Committee determines that the conditions precedent have been satisfied (or if the conditions that have not been satisfied are waived or modified), then (a) the vaccine submitted by the Developer to the Committee shall be deemed an **"Approved Vaccine,"** (b) the Developer of the Approved Vaccine shall be deemed a **"Designated Supplier,"** and (c) if requested by the Designated Supplier, the Funder shall enter into the Guarantee and Supply Agreement with the Designated Supplier within thirty (30) days of the date of the final, written determination of the Committee.[13]
13. Composition of Independent Adjudication Committee:	The Funder shall establish a committee (the **"Independent Adjudication Committee"** or the **"Committee"**), which shall comprise not less than [5] members. Members of the Committee will have expertise in the following fields: (a) immunization practices, (b) public health, (c) vaccinology and vaccine development, manufacturing and commercialization, (d) pediatric and internal medicine, (e) social and community attitudes on immunization, (f) economics, (g) contract law and (h) the vaccine industry, in each case, as applicable, with developing country perspectives. Members of the Committee shall serve a term of [_] years. Vacancies on the Committee will be filled by the remaining members of the Committee.
14. Actions of the Committee:	Each member of the Independent Adjudication Committee shall have one vote. Fifty percent of the members of the Committee, rounded up, shall constitute a quorum. Except as provided in Sections 10, 20 and 22, all decisions of the Committee shall be made by majority vote of the members at a meeting at which a quorum exists.

12. The Working Group recognized that it would be extremely costly to create an Independent Adjudication Committee that was fully capable of independently evaluating, approving and monitoring the Approved Vaccines and their ongoing production. Accordingly, the Framework Agreement permits the Independent Adjudication Committee to rely on third parties and their procedures, such as the WHO and its prequalification process.

13. As noted above, the Framework Agreement is designed to be self-executing with respect to the Funders, providing the Developers with the right to enter into the Guarantee Agreement on the terms specified in the Framework Agreement. The Framework Agreement is also designed to permit more than one Developer to receive funds under the Guarantee Agreement. For the reasons discussed in the Guarantee Agreement, and more fully in the report, the Working Group determined not to pursue a winner-takes-all approach.

15. Duties of the Committee:	The Committee will (a) seek to identify independent, unbiased and expert-qualified institutions and procedures to assist with determining whether a product meets the technical specifications and usability requirements and that can provide ongoing review of product safety and efficacy and manufacturing, (b) if necessary, designate Approved Regulatory Countries and Approved Manufacturing Countries from time to time, (c) evaluate products presented by Developers to determine if they satisfy the conditions precedent, (d) at its discretion or at the direction of Funder, waive or modify the application of specific technical specifications or usability requirements pursuant to Section 10, (e) if requested or as necessary, conduct multiple bilateral or multilateral meetings with Developer(s) in order to provide information about testing and acceptance procedures, waivers and modifications to the conditions precedent, market demand and supply forecasting, disease epidemiology and other relevant information,[14] (f) using the standards specified in Schedule B, determine whether subsequent vaccines are superior to the original Approved Vaccine, whether for certain target populations, epidemiological conditions or otherwise, and designate new Approved Vaccine(s) and new Designated Supplier(s), (g) after an Approved Vaccine has been designated, monitor the sales and use of such Approved Vaccine for ongoing compliance with the technical specifications and usability requirements set forth in Sections 8 and 9 and decertify any vaccine that is not in material compliance with such specifications and requirements, and (h) determine whether the technical specifications and usability requirements set forth in Sections 8 and 9 or the Maximum Guaranteed Amount or Funder's other payment obligations under the Guarantee and Supply Agreement should be modified in whole or in part based on *force majeure* criteria pursuant to Section 22.
16. Duties of Committee Members:	Each member of the Independent Adjudication Committee shall, in the exercise of its authority under the Framework Agreement, have the same fiduciary duties (including duty of care and duty of loyalty) as the director of a Delaware corporation.[15]
17. Contract Administrator:	The Funder shall retain one or more individuals (each, a **"Contract Administrator"**) to implement the decisions of the Independent Adjudication Committee and to perform such other administrative, support and other tasks as may be assigned by the Committee, subject to the approved budget for administrative expenses.
18. Budget:	The parties shall agree on a budgeting process to ensure that the reasonable expenses of the Independent Adjudication Committee and the Contract Administrators will be reimbursed by Funder.[16]

14. It is contemplated that the Developers would have the right to consult with the Independent Adjudication Committee, much the same way that companies consult with the FDA in the United States, to discuss the design of clinical trials, the structure of drug approval applications, the country or countries in which such approval will be sought, the possibility of granting waivers and other issues relating to the approval of an Approved Vaccine.

15. The duties of a corporate director under Delaware Law are the duty of loyalty, the duty of care and the duty of good faith. The duty of loyalty requires the director to place the corporation's interests above his or her own. The duty of care requires the director to act with certain minimum level of skill and deliberation. The duty of good faith requires that a director not act with bad faith, or engage in intentional misconduct.

16. A Funder's obligation to reimburse the Independent Adjudication Committee is subject to the requirement that its expenses be reasonable. A Funder may want to give further consideration to mechanisms that would permit it to regulate the cost of the Independent Adjudication Committee without compromising the Independent Adjudication Committee's independence.

19. Addition of New Developers to the Framework:	During the period beginning on the effective date of the Framework Agreement and ending [36] months thereafter, one or more entities may become parties to the Framework Agreement (*i.e.*, Developers) upon written acceptance of the terms of the Framework Agreement by such entity. Thereafter, additional entities may become parties to the Framework Agreement upon (a) written approval by the Committee if the new entity has technology or expertise that shows promise for the development of an Approved Vaccine, and (b) written acceptance of the terms of the Framework Agreement by the new entity; provided that no entity may become a party to the Framework Agreement with respect to a product after it commenced clinical trials for such product without the consent of the Funder.[17]
20. Addition of New Designated Suppliers:	The Independent Adjudication Committee may (by a 2/3 vote of its members and using the standards specified in Schedule B) determine that a newly developed vaccine satisfies the conditions precedent in Section 7, subject to its waiver and modification authority, and is superior to the previously selected Approved Vaccine, whether for certain target populations or epidemiological conditions or otherwise. Upon such a determination by the Committee, the Developer of the newly developed vaccine shall have the right to become a party to the Guarantee and Supply Agreement, whereupon the Developer of the new vaccine shall be deemed a "Designated Supplier" and the new vaccine shall be deemed an "Approved Vaccine." The addition of new Designated Suppliers and Approved Vaccines shall, in each case, be subject to the original Maximum Guaranteed Amount set forth in the Guarantee and Supply Agreement.[18]
21. Reserved Rights of Developer:	Developer reserves all rights, and the Framework shall not apply, to sales of any Approved Vaccine (a) outside the eligible countries identified in the Guarantee and Supply Agreement, and (b) in the military or travelers markets.
22. Force Majeure	In the event that there is a substantial change in circumstances with respect to [disease] in the countries identified in the Guarantee and Supply Agreement, including, without limitation, its incidence, its characteristics or methods for its treatment or prevention, such that the technical specifications outlined in Section 8, or the usability requirements outlined in Section 9 no longer achieve the original objectives, the Committee shall have the right (by a 3/4 vote of its members), using the criteria set forth in Schedule C, to (a) modify the technical specifications or the usability requirements, as applicable, (b) reduce the Maximum Guaranteed Amount or the Funder's other financial obligations to reflect changes in the number of eligible countries or the incidence of untreated [disease] in those countries, or (c) terminate the Framework Agreement. Unlike other decisions of the Committee, these decisions shall be subject to judicial review by an appropriate forum to determine whether the Committee abused its discretion.[19]
23. Representation and Warranties:	[TBD]

17. These procedures were intended to strike a balance between, on the one hand, permitting companies with promising technology or relevant expertise to participate in the Framework and, on the other hand, discouraging free riders who would operate outside the Framework and sign on only at the last minute. If companies do not sign on to the Framework, the agreement would lose its binding effect. Moreover, it would be difficult for the Funders to monitor the success of the Framework, particularly with respect to research and early development, without the periodic reporting by the Developer required under the Framework Agreement. Funders may wish to strike a different balance, such as allowing companies to join the Framework up until they commence pivotal trials.

18. The Working Group devoted considerable discussion to the question of whether more than one Developer would be permitted to receive payments under the Guarantee Agreement. On the one hand, the Working Group felt that it was important to preserve incentives for product improvements and that it would be important to use superior products should they be developed. On the other hand, the Working Group was concerned companies might be less willing to risk large investments in early research if they faced the prospect of entry of "me too" products offering no significant advance over the original vaccine. However, many of the industry participants interviewed by the Working Group indicated that they would prefer to have multiple suppliers over a winner-takes-all approach. Recognizing that independent research may lead to the development of substantially similar products, another option would be to permit any qualifying vaccines, whether or not superior, that are tendered within a window (*e.g.,* one year) after the approval of the initial Approved Vaccine to be accepted without showing superiority, provided that the second vaccine resulted from independent research and is not simply a generic copy.

19. The Framework Agreement for an early stage vaccine could be in force for a decade or more before a vaccine candidate is presented for final review to the Independent Adjudication Committee. Accordingly, a force majeure provision permitting the Funder to alter the Framework Agreement based upon extraordinary events has been included. The force majeure clause would void or alter the Framework Agreement in the event of major changes to technology, disease epidemiology or the like that make a vaccine either inappropriate or unnecessary or that would require a change in the specifications that would be more burdensome to the Developers. These determinations are subject to judicial review.

24. Indemnification and Insurance:	[TBD]
25. Term and Termination:	The term will begin on the date that [__] Developers have executed the Framework Agreement (the "Effective Date") and, unless earlier terminated pursuant to Section 22 or this Section 25, continue until the [_____] anniversary of that date, unless a Guarantee and Supply Agreement has been entered into prior to such anniversary in which case the term shall continue until the later of such anniversary and the expiration or earlier termination of the Guarantee and Supply Agreement. Funder shall have the right to terminate the Framework Agreement (a) after the [_____] anniversary of the Effective Date if no Developer has commenced GLP toxicology studies for a product that shows reasonable promise to become an Approved Vaccine, (b) after the [_____] anniversary of the Effective Date if no Developer has commenced clinical trials for a product that shows reasonable promise to become an Approved Vaccine, (c) after the [_____] anniversary of the Effective Date if no Developer has commenced a pivotal clinical trial designed to demonstrate that a product meets the technical specifications and the usability requirements for an Approved Vaccine, (d) after the [_____] anniversary of the Effective Date if no Developer has filed an NDA or other comparable filing for a product that meets the technical specifications and the usability requirements for an Approved Vaccine, and (e) after the [_____] anniversary of the Effective Date if no Developer has entered into a Guarantee and Supply Agreement with respect to an Approved Vaccine.[20]
26. Remedies in the Event of Breach:	[TBD]
27. Dispute Resolution:	[Arbitration under AAA rules in NY, NY].
28. Governing Law:	[New York law].
29. Waiver of Immunity:	If the Funder is a sovereign, it will (a) acknowledge that the transactions are subject to private commercial law, and (b) if it has not already done so, waive sovereign immunity.
30. Other Provisions:	Other covenants, terms and provisions as requested by legal counsel to Funder or the Developers.
31. Exhibits:	Guarantee and Supply Agreement.

20. The Funders have the right to terminate the Framework Agreement if certain interim milestones have not been achieved in a timely manner. This provision is included to provide the Funders with an option to end the agreement if the Framework does not appear to be stimulating productive research and development activities. This would permit Funders to pursue other, more promising opportunities.

Schedule A to model term sheet for Framework Agreement (Malaria)

Note that these specifications were developed for example purposes only. Further analyses and consultations would be required to arrive at the appropriate specifications for the actual guarantee.

I. Technical requirements

A. Indication:

1. Prevention of clinical episodes of Plasmodium falciparum malaria in infants and young children.

B. Target population:

1. 0–4-year-olds in areas of malaria transmission in Africa.

C. Efficacy requirements

1. Prevent at least 50% of clinical episodes of malaria due to P. falciparum.

D. Duration of Protection

1. At least 24 months with no qualitative or quantitative exacerbation of subsequent disease.

E. Interference

1. No interference with other pediatric vaccines.

F. Regulatory Approval and Quality Control

1. Regulatory approval of a product, with labeling that meets or exceeds the other technical specifications and usability requirements set forth herein, in one or more of Canada, France, Germany, Italy, Japan, [Mexico], Spain, the United Kingdom, the United States, [others] and such other countries with regulatory standards and procedures that are at least equivalent to those in the foregoing countries, as the Independent Adjudication Committee may designate from time to time (each, an **"Approved Regulatory Country"**). The Committee shall have the right to remove any Approved Regulatory Country if its regulatory standards and procedures change after the effective date of the Framework Agreement or the date that it was approved by the Committee, as applicable.

2. Manufacture of product in one or more of Canada, France, Germany, Italy, Japan, [Mexico], Spain, the United Kingdom, the United States, [others] and such other WHO-qualified countries with regulatory standards and procedures that are at least equivalent to those in the foregoing countries, as the Independent Adjudication Committee may designate from time to time (each, an **"Approved Manufacturing Country"**). The Committee shall have the right to remove any Approved Manufacturing Country if its regulatory standards and procedures change after the effective date of the Framework Agreement or the date that it was approved by the Committee, as applicable.

3. In lieu of one or both of the foregoing requirements, the Committee may rely on an independent, unbiased, expert third party (*e.g.,* the WHO) to determine that the product meets or exceeds the other technical specifications and usability requirements set forth herein, and to ensure that the facilities where, and conditions under which, the product is manufactured are in compliance with Good Manufacturing Practices and other applicable international standards with respect to the manufacture, holding and shipment of vaccines, in each case throughout the term of the Guarantee and Supply Agreement.

II. Usability requirements

A. Dosage:

1. 1 to a maximum of 4 immunizations; EPI schedule preferred.

B. Route of immunization:

1. Any, provided conducive to use on a large scale in Eligible Countries as defined in the Guarantee and Supply Agreement.

C. Presentation:

1. Multi-dose vials.

D. Storage

1. TBD.
2. TBD, e.g. Two years shelf life.

E. Safety Requirements

TBD, consistent with existing practices by UNICEF and PAHO.

Schedule B to model term sheet for Framework Agreement (Malaria)

Standards and Criteria

1. Standards for Addition of New Designated Suppliers
   TBD.
2. Criteria for Termination of Funder's Payment Obligations
   TBD.