Innovate UK

Results of Competition: **New Vaccines for Global Epidemics: Development and Manufacture**
Competition Code: **1602_SBRI_DFH_VACC**

Total available funding for this competition was £10,957,496 from the Department of Health

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
Prokarium Ltd	Rapid, simple manufacture and clinical evaluation of an oral plague vaccine	£1,035,557	£1,035,557

Project description - provided by applicants
As recent disease outbreaks show, the world needs to be faster and better at developing, manufacturing, testing and distributing vaccines. Prokarium, a UK-based vaccine development company focusing on oral vaccines, can move from bench to clinic 6-12 months faster compared to most injectable vaccines, use the same manufacturing process to produce a wide range of vaccines, cut costs by up to 70% and clinically test its oral vaccines under very simple out-patient conditions. Prokarium's delivery strain has established a strong safety record in 10 phase 1 and 2 clinical trials in 471 volunteers including 101 children. In this project Prokarium will clinically trial its next generation vaccine platform'Vaxonella', which when commercialised can be distributed at temperatures of up to 40 C for at least 12 weeks and which in emergencies can be self-administered without the need for medical personnel. These are the vaccine characteristics needed to combat serious diseases and potential epidemics such as plague caused by the bacterium Yersinia pestis. Historically plague was responsible for several epidemics, including the Black Death, which killed over 50 million people in Europe in the late medieval period. Today plague still kills people and in recent years the number of countries where plague is endemic increased, resulting in the World Health Organization labelling it a re-emerging disease. Coupled with the risk of future antibiotic resistant strains of Y. pestis arising, and its potential as an aerosol-delivered bioterrorism weapon, there is a need to develop an effective vaccine. An ideal plague vaccine must be designed for use in low- and medium-income countries to immunise high risk populations (e.g. Madagascar, DRC, etc.) on a seasonal basis and to rapidly distribute in response to an outbreak caused by major disturbances such as floods or earthquakes when the reservoir populations are disturbed. Prokarium's Vaxonella platform is based on live strains of Salmonella bacteria which are weakened so that they cannot cause disease. The Salmonella are taken orally as a capsule or liquid resuspension for children, they transit the stomach into the small intestine where they actively enter through the gut lining into the antigen-presenting cells of the immune system. The Salmonella to be used in this project have been programmed to express two protein antigens from Y. pestis from within the body's own immune cells. This targeted vaccination means all arms of immunity are triggered including the first line of defence, namely mucosal immunity. Also, manufacturing is up to 70% cheaper because costly purification needed for injectables is eliminated. Prokarium has already successfully tested a plague vaccine in mice. Now it will confirm that an improved vaccine can protect mice against Y. pestis, then rapidly manufacture a liquid suspension, and then test it on human volunteers in a clinical trial, where the safety and immune response will be measured. This will provide information to support further development of the plague vaccine and crucially be the first proof of concept of the next generation Vaxonella platform that could transform the way vaccines are developed, manufactured and distributed.

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University of Oxford	A phase I clinical trial of a Chikungunya vaccine using a single dose and no adjuvant	£976,757	£976,757

Project description - provided by applicants
The aim of this proposal is to progress a novel Chikungunya vaccine to a phase I clinical trial. Chikungunya virus (CHIKV) infections are characterised by severe joint pain and fever during the acute phase and long-lasting debilitating arthralgia during the chronic phase. Aedes mosquitoes, the vectors transmitting CHIKV have undergone a dramatic expansion, causing CHIKV to become a global threat leading to long-term economic impacts in endemic countries. Development of an efficacious CHIKV vaccine is an achievable goal partly due to the low antigenic variability of the virus. An ideal vaccine should be safe, cheap, highly immunogenic, adjuvant-free and able to induce long-lasting immunity after a single dose. No vaccine is yet available for the prevention of CHIKV infection. Of approximately 23 experimental vaccines, only 2 are currently being tested in clinical trials. One vaccine consists of a virus-like particle that presents antigens in a similar array to those of a virus but without replicating, stimulating immune responses better than a non-particulate protein. However, this approach requires multiple injections to induce seroconversion and reach high antibody titres, increasing the costs, making logistics more complex and limiting use in low-income countries. Another approach consists on a recombinant live attenuated measles virus (MV) expressing surface CHIKV antigens. The vaccine has been shown to be immunogenic and safe in humans but it also requires two doses to induce good immune responses. The Jenner Institute has designed a new vaccine platform consisting on a chimpanzee adenoviral vector, ChAdOx2, which has already been manufactured to GMP and will enter clinical trials before the end of 2016. Chimpanzee adenoviruses are genetically stable, can be thermostabilised for ambient temperature storage and are suitable for use in all ages of the population. A similar simian adenoviral vector, ChAd3 expressing ebola antigens was shown to induce high titre neutralising antibody titres equivalent to those induced by the replication competent VSV-vectored Ebola vaccine that demonstrated 100% efficacy in a phase III trial. We are proposing to perform a phase I clinical trial to assess safety and immunogenicity of a single dose of a ChAdOx2 vaccine expressing chikungunya structural antigens: capsid and envelope glycoproteins. CHIKV structural antigens have been shown to stimulate the induction of protective antibodies. Our preliminaty results indicate that our CHIKV viral vectored vaccine is highly immunogenic in pre-clinical models and is able to stimulate high titres of neutralising antibodies after a single dose, similar to titres induced in infected people.

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National Infection Service, Public Health England	Phase I Study of a MVA based vaccine for Crimean Congo Heamoraghic fever	£1,041,860	£1,041,860
Project description - provided by applicants			
Crimean-Congo haemorrhagic fever virus (CCHFV) is a deadly human pathogen and is of the utmost seriousness of being both fast acting and highly lethal. The virus has repeatedly caused sporadic outbreaks with a fatality rate of up to 80% and is commonly known as the Asian Ebola. CCHFV is transmitted most commonly by ticks and contact with infected livestock in addition to human-to-human transmission. The incidence of human CCHF cases closely matches the geographical range of permissive ticks. The virus causes outbreaks in Africa, Asia and Eastern Europe. Ticks that are able to transmit this deadly disease are encroaching into northern Europe infecting grazing livestock which is the CCHFV reservoir and an important part of the tick life cycle. Unfortunately there are no available vaccines or therapeutics to this disease. Public Health England scientists have extensive experience of working with this pathogen and developed an experimental CCHF vaccine called MVA-GP. This was produced by engineering a safe vaccine virus (MVA) to produce a key component of the CCHFV. In 2013, PHE published the results of successful trials that showed their experimental vaccine to be 100% effective at protecting animals against challenge with CCHFV. PHE has received funding from the UK Govt to develop the vaccine for animal use to enable widespread protection of farm animals which is a major source of infection to humans. PHE are now applying for funding to prepare clinical grade MVA-GP vaccine so they can perform a small clinical study to demonstrate the vaccine is safe and has the potential of protecting humans against this deadly disease.			

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University of Oxford	Addresing Efficacy of a Dengue vaccine candidate in a macaque challenge model	£488,611	£488,611

Project description - provided by applicants
Dengue virus (DENV) infects 400 million people a year. It is a leading cause of illness and death in the tropics and subtropics and its incidence is geographically expanding. Dengue and Dengue Haemorrhagic Fever are caused by any one of four DENV serotypes transmitted by mosquitoes and no licensed vaccines to prevent infection have become available worldwide to tackle all DENV at once. A major challenge in developing a DENV vaccine is to overcome virus variability because immune responses mounted to one serotype are not relevant to protect against the other 3 DENV serotypes. Furthermore, patients that previously suffered from dengue are in high risk to develop a more aggressive form of the disease if they come into contact with a different DENV serotype, as they have non-neutralising DENV antibodies -a process known as Antibody Dependent Enhancement (ADE) that promote DENV infection in a second exposure. Top-leading vaccines (B-cell vaccines) focus on the production of neutralising antibodies (humoral immune response) but pose a great risk to induce ADE in vaccinees and require multiple doses of complex polyvalent vaccines, becoming expensive and difficult to deploy in low-income settings. Importantly, those vaccines disregard the capacity of the T-Cell cytotoxicity to clear viral-infected cells (cellular immunity) in which ADE is not a concern. To date, a DENV T-cell vaccine has not been developed yet. After three years of R&D activities, we have designed and filed a patent (with Isis Innovation) of a set of T-Cell dengue vaccines, with the ability to recognise and mount strong cellular responses against highly conserved non-structural proteins across all four DENV serotypes. These DENV universal vaccines are contained in viral-vectored platforms such as Chimpanzee Adenovirus (ChAdOx1) and Poxvirus (MVA), which are highly immunogenic and safe in humans (i.e. they have been used in the latest Ebola Vaccine Trial in Oxford). The innovation of our development consists on the use of only one universal antigen to tackle all dengue serotypes and genotypes, using only two vaccine components and no adjuvant. This will contribute to the development of an affordable vaccine suitable for all endemic countries. Recently, we have assessed safety and T-cell immunogenicity elicited by one of our vaccines in Non Human Primates (NHP) at the Biomedical Primate Research Centre in the Netherlands. To date, NHP data have been essential for vaccines advancing to clinical trials, based on neutralizing activity in serum and/ or reduction of post-challenge viremia, which indicates to vaccine developers and regulatory agencies of the potential for efficacy in humans. Our goal now is to take forward our DENV vaccine development to explore its ability to confer efficacy protection against a reproducible DENV challenge model in macaques at the Caribbean Primate Reseach Center in Puerto Rico, where this DENV challenge is widely used to test DENV vaccine developments. Accomplishment of this goal will allow us to apply for a streamline funding to support a Phase-I clinical trial.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Themis Bioscience GmbH	A single dose ambient temperature stable vaccine for the prevention of Zika virus	£999,180	£999,180

Project description - provided by applicants

The last 12 months has seen rapid spread of the Zika virus from Africa and Asia to the Americas with over 30 countries in this region now reporting Zika virus infections. The majority of these south and central American territories have high levels of poverty. While infection with this virus is rarely fatal, the virus has been associated with causing Guillain-BarrÃ© syndrome. This disease leads to long term damage of the nervous system. Furthermore, the virus is also associated with causing congenital microcephaly of new-born babies where the mother acquired a Zika virus infection during pregnancy. Consequently, there is a demand for a vaccine suitable to combat Zika virus infection particularly in low-income settings where infection rates are highest. We propose to develop a vaccine from a pre-existing attenuated live measles vector strain that has been administered safely to hundreds of millions of people, mostly children, without relevant safety concerns. Moreover, this system has recently been used for another experimental measles-vectored vaccine that was proven as safe and resulted in an excellent clinical response. This vector is genetically engineered to express Zika virus proteins intracellularly that will allow a single dose to be effective with the vaccine providing persistant durable immunity over the long term. The vaccine will be used in low to middle income settings where there will be limited or intermittent cold chain capabilities. Therefore, the vaccine will be formulated using a novel silk fibroin technology. This technology will be evaluated over 12 months on its ability to confer stability to the vaccine even when exposed to high temperatures (>30 Celsius). Furthermore, the existing high yield production system allows a reduction in the cost of goods for low income settings. Within 18 months of the project start, a Zika vaccine will be fast-tracked for safety and efficacy assessment in a phase I clinical trial based in Europe. The vaccine's effectiveness to protect will be assessed based upon the ability of the serum from the vaccine recipient to neutralize wild type Zika virus in an animal model. Finally, an in-vivo bridging study will demonstrate equivalency of the existing and the high stability formulation.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
University of Oxford	Protective efficacy and neutralisation to select an optimal Zika virus vaccine	£498,870	£498,870

Project description - provided by applicants
Zika virus (ZIKV) is an emerging Flavivirus transmitted by Aedes mosquitoes that is now rapidly spreading throughout South, Central and North America. ZIKV is a major concern worldwide due to the neurologic conditions, such as Guillain-BarrÃ© syndrome in French Polynesia, and a concurrent 20-fold increase in the incidence of microcephaly during the ZIKV outbreak in Brazil between 2014 and 2015. Unfortunately, no vaccine to prevent infection is currently available. We have recently developed two new vaccine platforms suitable for human use, based on replication-deficient chimpanzee adenoviral vectors ChAdOx and Modified Vaccinia Ankara expressing various versions of Zika structural antigens. We have started evaluating the immunogenicity of our vaccine candidates using ELISA and cellular assays, such as ELISPOT. Here, we propose to extend those studies to use functional assays such as neutralisation of viruses and infection of pre-clinical models to select the optimal vaccine candidate for a clinical trial in the near future. Our proposal aims are: (1) Compare the protective efficacy of 10 novel vaccines produced at the Jenner Institute, using pre-clinical models suitable for infection with ZIKV at the Public Health England laboratories; (2) Measure the ability of vaccine-immune sera to neutralise ZIKV entry using in vitro cell cultures to establish quantitative neutralising antibody titres required for protection in mice; and (3) Identify antibody titres in samples from infected volunteers in Mexico to define titres induced during acute infection and convalescent period of the disease, and thus define titers of physiological relevance for a vaccine candidate. We will combine laboratory data with field data obtained from areas with prevalence of ZIKV infection, supported by infrastructure of Oxford NDM-Mexico collaborative laboratories, a network dedicated to the study of emerging infectious diseases. The information obtained at the end of this study will be key to inform vaccine development and confirm the most immunogenic and protective ZIKV vaccine candidate that would be suitable for a clinical trial. This project will also strengthen new synergistic links between the PHE (https://www.gov.uk/government/organisations/public-health-england), Oxford Biochemistry Department (http://www.bioch.ox.ac.uk), Oxford Vaccine Group (http://www.ovg.ox.ac.uk), Oxford NDM-Mexico network for emerging pathogens (http://www.ndm.ox.ac.uk/mexico/home) and the Jenner Institute (http://www.jenner.ac.uk/home) that will be invaluable for the UK capability to respond rapidly to emerging infections.

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BG Research Ltd	Differential diagnostics of haemorrhagic fevers in resource poor environments.	£654,717	£654,717

Project description - provided by applicants
This project centres on the proof of concept of a simple, rapid diagnostic platform for the differentiation of viral haemorrhagic fevers in resource poor environments. The benefits of this approach; 1. Simplicity, requiring only a fingerprick of blood. 2. Reduced time to detection, from blood to result in around 30 mins. 3. Suited to resource poor environments, removes the requirement for lab facilities or cold-chain.Portable and as such can be used in remote areas. 4. A molecular diagnostic assay, the system can differentiate and quantify a large number of viral targets and be sensitive enough to detect down to the 1000 viruses per ml level. 5. Reduced costs per test, removing the requirement for a lab while allowing high level multiplexing make the approach compare well with multiple immunological based tests while providing viral load information. 6. Reduced hazard risk in testing to the medical professional; assay process is easy to use even with users deploying bio-hazard ptotection and the assay is closed tube. During the recent Ebola outbreak BG Research (BGR) was tasked with adapting its technology for the direct detection of sepsis causing organisms to the rapid, closed tube detection of Ebola in remote areas. The approach migrated the proven CDC assay onto a novel instrument capable of detecting down to as low as 20,000 viruses per ml of blood - the same sensitivity as the laboratory based approach. That project adapted existing BGR instrumentation into a new technology demonstrator and the goals of this project are to develop a new prototype featuring a larger reaction volume such that the sensitivity can be improved by over 20 times - enough to potentially detect infection in convalescent patients and to monitor close contacts of infected patients not yet displaying symptoms. The main goals of the project are firstly to demonstrate a novel first step that concurrently renders the virus non-infectious while releasing the viral RNA - this involves rapidly freezing and thawing the blood sample in a buffer containing an RNA stabilising biocide. The whole process takes place in a single tube and during this project a large reaction vessel, capable of analysing 5 times more blood than the Ebola technology demonstrator is the 2nd goal. A prototype instrument, capable of in-field use and able to process multiple samples concurrently in a random access manner will be designed. Lastly, assays will be developed to demonstrate the system's capability to differentiate large numbers of different viral targets concurrently in a multiplexed assay. This is a platform technology, but the final assay chosen here will be an RT-QPCR molecular differential assay for Ebola, Lassa, Marburg, Crimean-Congo fever and Rift valley fever to be tested on live virus at PHE Porton. The platform technology can be adapted to other blood-borne diseases such as Zika, Dengue, Chikungunya and Malaria dependent on regional requirements.

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Mologic Ltd	Improved Q Fever Vaccine (DSTL, PHE, ICENI DX & Mologic)	£522,800	£522,800

Project description - provided by applicants
Virus-like particles (VLPs) are a flexible delivery platform that provides potential for presenting multiple antigens to the immune system concurrently. Hepatitis B core antigen self assembles to form highly stable, immunogenic VLPs in a relatively low cost yeast expression system. The viral protein can be adapted to display foreign antigens on spikes that protrude from the surface of the VLPs. This technology circumvents the need for high cost, high containment production facilities, cold transportation and storage. Our goal is to produce a cost effective, second generation Q fever vaccine, using VLP technology as a production platform. In initial proof of concept studies, the Mologic-Dstl-Iceni Diagnostics consortium has successfully produced and tested Burkholderia pseudomallei vaccine candidates based on yeast-produced VLPs presenting either peptide or polysaccharide antigens. These candidates were efficacious in a mouse model of Melioidosis, demonstrating the readiness of this technology for roll out for antibacterial vaccine production. In the current proposal, we will consolidate and extend our work on this platform, applying it to Coxiella burnetii, the causative agent of Q Fever, which is listed as an agent of concern by the WHO and UN. Q fever is found worldwide and there is high prevalence in low income countries. This VLP platform bid will draw on expertise in Coxiella burnetii antigenicity to develop a vaccine against Q fever. It has been shown that C. burnetii lipopolysaccharide (LPS) provides protection against challenge, indicating that it is a key protective antigen. LPS itself is a T-cell independent antigen; conjugation to a protein carrier can improve antibody isotype development and crucially stimulate B cell memory. Therefore, to increase vaccine efficacy and develop immune memory to Coxiella, we propose conjugating native C. burnetii LPS, or synthetic fragments thereof, to VLP carriers. In parallel, we will express previously identified C. burnetii protein surface antigens on VLPs, providing material for potential blending with LPS-VLP conjugates to produce multi-antigen vaccines. The novel VLP vaccines produced in this study will be tested in our established mouse model of C. burnetii aerosol infection; immune responses will be determined and related to the vaccine efficacy. Several VLP vaccines have already been licensed for human use, demonstrating an established path to market. The opportunity to manufacture without high level containment will result in inexpensive vaccines where manufacture can be transferred to low income settings. This will serve to pave the way for future development of low-cost vaccines for other globally significant pathogens.

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Stabilitech Ltd	An Oral Zika Vaccine	£214,270	£214,270
Project description - provided by applicants			
Oral delivery of low cost viral Zika vaccine antigens which generate authentic humoral responses. The ability to deliver a vaccine orally in a reliable manner has several obvious advantages. However, barriers exist which limit this route of administration. Two of the main barriers include the highly acidic environment in the stomach and the hold time of products entering the stomach (up to 5 hours) during which time the temperature is a constant 37°C. Technology to apply enteric coatings to substances to ameliorate the acidic challenge have been available for a considerable time, however the ability to overcome the thermal barrier has been not been available until now and represents a significant technical formulation challenge limiting the broader use of the orally administered viral vectored vaccines. Stabilitech has a novel stabilisation platform which protects fragile vaccines and biologics not only during processing and storage, but also as recently demonstrated when administered to subjects orally. We propose to build upon our pilot data in which we have used adenovirus 5 delivery to the duodenum for expression of green fluorescent protein which in addition demostrated an antibody response to the GFP but no neutralising responses to adenovirus. The proposed series of investigations will undertake experimental studies to develop a novel Zika virus vaccine which would be administerable via oral tablets. This vaccine would have multiple additional benefits due to its inherent thermal stability which would impact on the whole supply chain and relieving the pressure on product supplies, healthcare providers and importantly would be very amenable to developing countries due in part to the cost savings generated from the ease of administration, production, transport and storage.			

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Plymouth University	A Conditional System for Inexpensive Manufacture of Attenuated Vaccines	£156,181	£156,181
Project description - provided by applicants			
Emerging infectious diseases (EIDs) with a potential for substantial and wide spread human mortality are an increasing threat to global stability. EIDs of global significance are most commonly caused by viruses - many of which have never been seen prior to their emergence into the human population. The level of societal disruption associated with the recent Ebola virus outbreak in West Africa gives only an indication of the potential impact of these viruses: only a slight increase in the capacity of an emerging virus with a similar mortality rate to spread will be far more devastating. Vaccination is a cost-effective method of EID control. However, most of these viruses emerge in poorer, low income countries where cost of vaccine production is prohibitive to widespread vaccination without foreign intervention. High-income country vaccine sourcing is a serious impediment to widespread adoption of vaccination by the local population, and also undermines the empowerment of middle/low income countries to permanently resolve their own societal and healthcare problems. The aim of the current proposal is to develop a vaccine platform that is suitable for development to target emerging viruses in low income countries. This vaccine platform will be inexpensive, easy and quick to manufacture, provide long-lasting and effective protective immunity after only a single or few doses, have a high safety profile, and be suitable for broad application against multiple different viruses.			

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Cell Guidance Systems Ltd	Polyhedrin-encased glycoproteins as novel cold chain independent vaccines	£486,701	£486,701

Project description - provided by applicants
The majority of vaccines have a narrow temperature window within which they must be stored to maintain functionality. The development of vaccines that are stable at ambient temperatures is a major challenge in their delivery to the people that need them the most, in low-income settings where the refrigeration infrastructure required is poor. We have developed an innovative vaccine manufacturing system, based on a patented protein production mechanism. This system exploits the unique properties of the polyhedrin protein naturally expressed by the silkworm (Bombyx mori) cypovirus. The polyhedrin protein forms large, temperature-stable and pH-stable crystals within infected insect cells. These crystals attach to, and subsequently encase, mature cypovirus virions. This results in enhanced stability and viability of the virion, leading to a markedly longer window of infectivity. Genetic engineering techniques have been used to adapt this viral survival mechanism to encapsulate any given tagged recombinant proteins by co-expression with polyhedrin protein. This in-vitro insect cell expression system is known as PODS (POlyhedra Delivery System). PODS provides key advantages for vaccine production, including (1) rapid development, to address emerging viruses, (2) scalability of manufacture, and (3) inherent stability of cargo protein structure, even over extended periods in warm and wet conditions, eliminating the need for cold-chain supply and the need for frequently repeated, more costly manufacturing schedules. The aim of this study is to develop a vaccine delivery platform based on PODS. The project will have 3 streams: 1) Develop PODS encoding and encapsulating glycoproteins from a range of priority pathogens with pandemic potential and confirm temperature stability of PODS vaccines over an extended time. 2) Test PODS for their ability to induce neutralising antibodies. 3) As a proof of concept, test PODS vaccines for their ability to protect against infection. We will examine three viral infections based on prioritization by UKVRDN and based on our expertise: (1) Zika virus, an emerging pathogen linked to malformation of the brain in children of mothers infected during pregnancy. (2) Ebola virus, a viral hemorrhagic fever that has caused the death of >11,000 individuals in West Africa since December 2013. (3) Lassa fever, an acute viral haemorrhagic illness that is endemic in the rodent population in parts of West Africa which causes illness in 300,000 individuals each year with around 5,000 deaths as a result. By the end of these initial studies, we aim to obtain proof of concept that the PODS platform can be used to generate temperature stable vaccines capable of inducing a potent neutralising antibody response. Having shown the efficacy of the vaccine we plan to move to GMP production of PODS in a phase II application.

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Prokarium Ltd	An affordable, oral vaccine against mosquito- and sexually-transmitted Zika virus	£394,407	£394,407

Project description - provided by applicants
In February 2016 the WHO declared the Zika virus (ZIKV) to be a 'Public Health Emergency of International Concern'. Experts now believe ZIKV is linked to a broad set of complications in pregnancy, including miscarriage, stillbirth, premature birth and eye problems with 29% of scans showing abnormalities in babies in the womb, including growth restrictions and microcephaly, in women infected with ZIKV. To clear viruses, the body generally requires both systemic and cellular immune responses, but unlike most insect-vectored diseases, ZIKV can also persist in semen and has been shown to spread as a sexually transmitted disease. That means mucosal transmission by travellers returning from any of the 43 endemic countries (population 525 million; 66 million tourists p.a.) may bring back and spread the disease in non-endemic countries. ZIKV has also been found in other bodily fluids including saliva and urine. Therefore, a vaccine that triggers systemic, cellular and mucosal immunity is needed, and preferably one that is easily manufactured and distributed under many different conditions. Prokarium's oral vaccine platform, Vaxonella, mimics an intracellular pathogen and expresses vaccine antigens from within the immune cells of the gut lining. This means Vaxonella triggers all arms of immunity while reducing manufacturing costs by up to 70% due to the elimination of downstream purification of protein, which is always needed for injectable protein vaccines. In addition, Prokarium has developed a dried formulation of Vaxonella that is thermostable at 40 C for up to 12 weeks. These qualities are specifically suited to ZIKV and distribution to endemic areas as well as travellers, as Vaxonella vaccines can be produced almost anywhere and be self-administered. This temperature stability and self-administration will be useful in remote areas lacking medical personnel, but also for travellers if a booster is needed, as most travellers do not prepare ahead of time to take several doses of vaccine. Vaxonella is based on live strains of Salmonella bacteria that are weakened so that they cannot cause disease. The Salmonella are taken orally as a capsule (or as a liquid suspension for children); they transit the stomach into the small intestine where they actively enter through the gut lining into the antigen-presenting cells of the immune system (mimicking an intracellular pathogen). Using Prokarium's proprietary genetic technologies, the Salmonella to be used in this project will be programmed to express protein antigens from ZIKV, and tested in mice to study the level of immune response generated. The best candidates will then be used to immunise mice which will be challenged with the actual ZIKV, using the existing subcutaneous challenge model at Public Health England (to mimick the mosquito bite route), who will also develop a novel vaginal challenge model (mimicking the sexually transmitted route), to see if they are protected compared to unvaccinated control mice. This will provide information to support further development of the ZIKV vaccine for future evaluation in human volunteers and represents the first known attempt to make a ZIKV vaccine that has a high chance of preventing both the insect-vectored and sexually transmitted versions of the disease.

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Innovate UK

Results of Competition: **New Vaccines for Global Epidemics: Development and Manufacture**
Competition Code: **1602_SBRI_DFH_VACC**

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Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
National Infection Service, Public Health England	LassaVacc	£593,928	£593,928

Project description - provided by applicants
This project will generate and test a vaccine for Lassa Fever (LF), for which there is currently none available. LF is a haemorrhagic fever common in West Africa, caused by Lassa virus (LASV). In addition to causing approximately half a million cases with over 5000 deaths a year, LF is regularly imported into Europe, often into the UK. The proposed vaccine will be a live virus based on the widely used orthopox Modified Vaccinia Ankara (MVA), which does not grow in humans. MVA will be genetically modified to express the capsid and surface glycoproteins from LASV. This will result in the induction of an appropriate and protective immune response. In this work the immune response will be examined in'humanised' mice which possess a human immune system. LASV is naturally reservoired in rodents and normal laboratory mice remain resistant to LF. In consequence, past research has been limited to the use of guinea pigs which complicate mechanistic studies on immunity. Following the assesment of the induced immune response in humanised mice we will conduct a vaccintion - challenge study with wild type LASV. Research Objectives 1) Create an MVA Lassa virus capsid - glycoprotein construct (MVA-LassaVacc). 2) Develop a challenge model in humanised mice to test the efficacy of Lassa virus vaccines. 3) Determine the immune response of the MVA-Lassa construct in humanised mice. 4) Test the MVA-Lassa construct for protection in the humanised mice challenge model. PHE-Porton is a WHO Collaborating Centre for the most dangerous virus pathogens such as LASV. As such it has access to a wide range of laboratory strains and active links to colleagues in the field who can provide circulating strains. MVA with full freedom to operate is also available at PHE-Porton. Indeed PHE-Porton has a successful background of work on vaccine candidates based on MVA for other pathogens such as Crimean-Congo Haemorrhagic fever virus. Significantly PHE-Porton has a track record in producing attenuated orthopoxvirus vaccine candidates ' including vaccinia Lister which has been manipulated in the past to construct an efficacious Lassa vaccine candidate. The vaccinia Lister approach is limited however, because it cannot be used with immunocompromised idividuals such as those in many parts of Africa who have HIV. Nevertheless, we can now build on this experience by adopting the highly attenuated MVA platform which has a proven safety history, including in immunocompromised patients, since its use in over 100,000 doses in humans during the smallpox eradication campaign of the 1970s. It is also amenable to large scale GMP manufacture, does not require a cold chain and is thus suited to use in low resource settings.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Excivion Ltd	A Dengue/Zika Vaccine That Avoids Antibody-Dependent Enhancement	£500,000	£500,000

Project description - provided by applicants

The present project provides a solution to the principal problem of dengue vaccine development, wherein the use of licensed (and soon to be licensed) vaccines based on existing vaccine strategies runs the risk (in a finite number of cases) of giving rise to 'antibody dependent ehnancement' of dengue infection, making it worse rather than preventing it. Enhancement is a feature of natural infection (where antibodies sent to neutralize the virus are subverted to gain access to human bodily cells), usually upon encounter with a second 'serotype' of virus, resulting in more severe symptoms. Vaccination, while for the most part conferring protection, is liable also to give rise to cases of the severe 'dengue haemmhoragic fever' (DHF), upon first exposure to a wild dengue virus: i.e. 'iatrogenic' cases of DHF, which would not have occurred but for the vaccine. Furthermore, existing vaccine approaches also have the potential to create a population of vaccinated individuals who develop iatrogenic-DHF, at some interval after the vaccine (or vaccine course) has been administered (eg. several years). This is because, as immunity to dengue wanes, protective antibodies reach a concentration where they 'enhance' rather than prevent infection. Also, the rate of decay of 'immunological memory' (where the immune system recalls encounter with a wild virus or vaccine shot) is not synchronous for the four serotypes of the vaccine, such that immunity to each serotype of dengue is lost at different times, successively increasing the risk of severe disease. This gradual failure of immune memory likewise creates a new population of individuals who are now predisposed to DHF (when bitten by an infected mosquito), instead of protected, as a result of previous vaccination. The solution is to make a vaccine that has zero or minimal propensity to give rise to 'antibody dependent enhancement', while preserving efficacy, in a manner amenable to incorporation into several of the various vaccine formats now in existence (live vector, DNA vaccine, oral vaccine, subunit vaccine etc.). For the purposes of this project zika is accorded the status (metaphorically speaking) of a 'fifth dengue serotype'. This is because dengue infection (and current dengue vaccines) have the potential to facilitate the spread of zika by generating infection-enhancing antibodies which also react with zika virus. The object of this project is to generate a safer dengue vaccine with zika built in - in order to avoid the risk of vaccine-mediated facilitation of pandemic spread of zika infection by dengue vaccination. Given the immense societal need and interest on the part of governments and pharma/vaccine companies in vaccinating against dengue and related virus infections, the intellectual property going into this project and generated by it, will become a valuable commodity for new vaccine developers seeking competitive advantage in the marketplace based on safety. 'Safety' will become a criterion of increasing value given the complexities of new epidemics of related viruses (such as the present zika pandemic) and how they interact with national vaccination programmes. The role of natural dengue infection in paving the way for pandemic zika infection has been elaborated recently by Philip K Russell of the Sabin Vaccine Institute (PLoS Negl Trop Dis. 2016 Mar 18;10(3)). Current vaccines may meanwhile be of substantial 'net' benefit to public health, but the safer option promised by the present proposal has the potential to win out.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Nova Biopharma Technologies Ltd	Room temperature stable MVA-GP pox vectored vaccine against CCHF	£428,646	£428,646

Project description - provided by applicants

The objective of the proposed programme is to achieve a room-temperature stable, ready-to-inject vaccine against Crimean-Congo haemorrhagic fever (CCHF). HydRIS (Hypodermic Re-hydration Injection System) stabilisation platform with a proven track record of successfully stabilising live viral and bacterial vectors will be assessed to stabilise MVA-GP vaccine- a novel pox-vector based vaccine against CCHF developed by the Health Protection Agency. The successful completion of the programme will enable to develop a CCHF vaccine that will not rely on the cold-chain-distribution, which is especially challenging in certain parts of the world vulnerable to CCHF. As a platform technology, this programme will further demonstrate the applicability to a range of MVA-vectored vaccines. Nova Biopharma Technologies part of Nova Group continue to develop cutting edge technologies supported by it's advanced manufacturing capabilities for both clinical and commercial manufacturing scales. PHE exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health. PHE Porton undertakes basic and applied research into understanding infectious diseases, with expertise in high containment pathogens. PHE Porton specialise in translational research to develop and test interventions for public health, including new products such as vaccines and diagnostics.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
University of Cambridge	Emerging Viral Vaccine Antigen Insert Consortium (EVAC)	£498,379	£498,379

Project description - provided by applicants
Of the emerging and re-emerging diseases a disproportionate number (37%) are caused by RNA viruses (Heeney, J Internal Med, 2006), notoriously variable due to their intrinsically high mutation rate. Vaccines are only as good as the immune targets (antigens or gene inserts) of the pathogen that they encode. In most cases current vaccine candidates against RNA viruses are limited by the viral strain used as the vaccine insert, which is often chosen based on availability of a wild-type strain rather than by informed design. By bringing together cutting edge technologies we can achieve dramatic improvements in vaccine efficacy against new viral variants based on outbreak sequence data to generate synthetic optimised vaccine inserts to give the broadest possible vaccine protection against future outbreaks of variable RNA viruses. We will generate new vaccine candidate inserts for a wide variety of emerging and re-emerging viral agents including Ebola, Marburg, Lassa, Zika, MERS, Chikungunya, Dengue and others. Our new platform vaccine technology merges (1) sequences of outbreak pathogens, (2) broadly anti-viral neutralising monoclonal antibodies (BNmAb) derived from outbreak survivors, (3) computational modelling methodologies, (4) synthetic gene technology and antigen display technology, (5) high throughput viral binding and neutralisation screens, and (6) in vivo immune selection and vaccine efficacy readouts. The end products are novel immunogens to trigger the broadest spectrum of protective immune responses using Digitally Designed, Immune Optimised and Selected (DIOS) vaccine inserts against emerging/re-emerging RNA viruses. Towards this goal we propose two streams: Stream I) Proof of concept (this application). Within 12 months, we will demonstrate proof of concept by targeting the broader family of Ebola viruses by delivering next generation vaccine inserts designed to be slotted into existing clinically trialled vaccine vectors to compare improvements in immune responses, the breadth of protection, durability and efficacy. We will deliver new DIOS vaccine inserts into existing candidate Ebola vaccine vectors to enable direct comparison in head to head clinical trials. Stream II) During stream 1 we will have established proof of concept and prepared our technology pipeline to address other outbreak RNA viral disease vaccines needs such as Lassa Fever virus and Zika virus. The collaborating team has the technology operational (under previous Gates Foundation/HIV funding) and we have a proven track record of working together and delivering (Ewer et al, NEJM, 2016). This new platform will improve the UK's vaccine arsenal to emerging viral diseases, and ensure that the UK is at the forefront of the global fight against future disease outbreaks.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Oxford Expression Technologies Ltd	Development of an economically viable CCHF virus vaccine for local production	£217,428	£217,428

Project description - provided by applicants
Some of the deadliest diseases we know about occur in areas of the world least well equipped to deal with them. The fact that they rarely cause problems in developed countries has hampered the production of preventative vaccines. Interest in these so called neglected diseases is limited owing to the small markets involved and poorly resourced healthcare. An example is Crimean Congo haemorrhagic fever (CCHF) virus, a severe disease that outbreaks sporadically in Africa, the Balkans, the Middle East and Asia. The virus is spread to humans via tick bites or contact with virus-infected animals, which rarely suffer disease, or other virus-infected humans. Flu-like symptoms develop within a week, with progression in 75% of cases to signs of haemorrhage including nosebleeds, vomiting and black stools. The liver becomes swollen and painful. Kidney function can also be affected with failure in the most severe cases. The mortality rate for the disease is 10-40%. One of the problems in developing such a vaccine is that as CCHF is so hazardous, any studies to produce a vaccine based on the intact virus must be conducted in specialized, high containment facilities. Although vaccines may be derived from inactivated, non-infectious CCHF virus, these have been shown to be toxic. An alternative approach is proposed in this project. We will use information about the genetics of CCHF virus to design a synthetic gene that has the code for making a protein component of the virus that in the course of an infection in humans results in the production of protective antibodies. This will be inserted into the DNA of an insect virus that is harmless to humans and because of other genetic modifications can no longer even infect its natural insect host. However, this modified virus can still be amplified in vats of insect cells grown in artificial nutrients. Simultaneously, it also produces the protein from CCHF virus. This can be isolated from the insect cells, purified and used subsequently in trials to determine if it is a suitable candidate for use as a vaccine. While initially producing the prototype CCHF virus vaccine is a complicated procedure, which requires a specialist laboratory-based facility, its subsequent use is not. All of the procedures necessary to use the prototype can be mimicked in a much simpler facility, using only basic scientific and production equipment. It is the aim of this project to develop CCHF virus vaccines that can be produced locally, where they are needed. The platform technology we develop will also be readily transferable to make vaccines for a number of other diseases related to CCHF virus that are likely to pose significant problems for human populations in the next few years.

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Competition Code: 1602_SBRI_DFH_VACC

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Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
Proxima Concepts Ltd	Self-Administered Vaccines Directed Against Plague and MERS	£495,000	£495,000

Project description - provided by applicants

The objective of this proposal is to develop a technology platform for producing safe, temperature-stable vaccines for global diseases. A particular focus will be self-administered delivery by oral vaccination because this can be carried out efficiently in resource-poor settings and is highly desirable to prevent serious endemic diseases in at-risk populations. Using our innovative oral vaccine formulation technology, we intend to formulate recombinant protective antigens to protect against the serious diseases of MERS and plague for which no licensed vaccines currently exist. The applicant, Proxima Concepts Ltd, will supplement its in-house formulation expertise with input from contracted partners that have state-of-the-arts capabilities in recombinant antigen production, preclinical vaccine testing (DSTL), protein antigen stabilisation (XstalBio) and vaccine manufacture and process development to clinical production (Porton Biopharma Ltd). This combined expertise will enable us to demonstrate the scientific and technical feasibility of developing a candidate vaccine for each of the indications over the 12 months of the project. In addition the project is designed to generate sufficient pre-clinical data to support the planned transition towards clinical development. The basic concept for these vaccines is that an injected priming dose would be administered by trained medical personnel in a health centre. The patient would then return home and subsequently self-administer the boost(s) by taking an enteric-coated capsule containing an oral formulation of the same vaccine This programme of work will produce stable vaccine formulations which can be rapidly and cost-effectively manufactured in an emergency situation and quickly deployed in potential epidemic areas. The combination of an injected prime and oral boost is an innovative approach to vaccines for prevention of respiratory infections but could potentially provide a platform for protecting against other epidemic diseases.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
University of Oxford	Development of a novel vaccine for rapid response against Plague	£359,777	£359,777

Project description - provided by applicants
The aim of this project is to create a novel and innovative vaccine against plague (Yersinia pestis) by using a potent vaccine delivery technology highly suitable for outbreak situations in low-income countries. Plague is a highly contagious and virulent infectious disease transmitted to humans by flea bites. Since the 1990s, the number of human plague cases has increased in 25 countries, and plague is now classified as a re-emerging infectious disease for: 1. the presence of large reservoirs in African, Asian and American continents, 2. its endemicity throughout the world resulting in sporadic infections, including recent outbreaks in the 21st century, 3. the requirement to start antibiotic treatment of pneumonic plague within 24 h after the onset of symptoms (otherwise 100% fatal), 4. its potential use as a bioweapon due to its extreme virulence and ease of spreading (through aerosol), and 5. the recent emergence of antibiotic-resistance strains. Vaccine development efforts against plague have been dominated by the use of live attenuated vaccines and sub-unit proteins. Live attenuated vaccines pose significant safety concerns and the level of protection achieved is debated. Sub-unit proteins in adjuvant have demonstrated a certain degree of protection in animal models, but the immune response seems limited to antibodies while a cellular response correlates with increased efficacy. These vaccines have however greatly contributed to the identification of immune correlates of protection. In this context, our proposed solution is to use viral vectors as a delivery platform. We propose to use this type of vaccine technology, for the first time, based on harmless replication-incompetent viruses, currently developed against numerous infectious diseases including Ebola, malaria and HIV, but not yet investigated for plague. This technology is highly suitable for diseases for which cellular immune response are required for protection, in addition to antibody responses, and is also suited to outbreak situation in low-income countries (as for the recent Ebola outbreak, where all vaccines developed were based on viral vectors). We will use several plague proteins known to elicit protective immune responses and insert them into our latest and most potent viral vaccine vectors, which we found to be highly immunogenic in recent clinical trials including against flu and Ebola. Our group has expertise in delivering bacterial proteins to the immune system by inserting them into such viral vectors including adenovirus (usually responsible for colds) rendered harmless by genetic modification. We will investigate the immune responses and level of protection induced by these novel vaccines in animal models and identify the most potent candidate. If successful, this project will provide a strong case for testing of this new plague vaccine in people

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
University of Oxford	'Plug and Display' Virus-like Particle Platform for Rapid Response Vaccination'	£394,427	£394,427

Project description - provided by applicants
Virus-like particles (VLP) are a platform technology that are used to produce vaccines against many different diseases. These technologies are particularly suited for the induction of strong antibody responses, which they achieve through presentation of an ordered antigen array to the immune system. Many different types of VLP vaccine have been tested in preclinical studies and some licensed vaccines employ this technology, such as the hepatitis B vaccine. The Jenner Institute and Biochemistry Department at the University of Oxford have recently established a platform VLP vaccine technology for irreversibly decorating VLPs simply by mixing with protein antigen in a "plug-and-display" manner. Critically, this approach overcomes the well-described challenges of producing VLP carriers with complex antigens genetically-fused on their surface, or low conjugation efficiency often reported when using chemical conjugation. In this project we will generate VLP vaccines that display key target antigen from outbreak viral pathogens. In order to do this, we will make use of the novel SpyCatcher-SpyTag technology platform to 'plug-and-display' target antigens on the VLPs. This technology allows for the rapid and efficient formation of a spontaneous isopeptide bond (irreversible linking) between the small SpyCatcher (10 kDa) on the VLP carrier surface and a short versatile 13 amino acid SpyTag incorporated within the antigen. This strategy is versatile and particularly useful for rapidly generating VLP vaccines to emerging and outbreak pathogens of public health concern. We will initially generate a universal VLP carrier that can be utilised for this technology platform. In parallel we will express the Ebola, Marburg, Zika and Chikungunya virus glycoproteins fused to SpyTag, fuse them to the VLP carrier, and test the immunogencity and in vitro immuno-efficacy providing comparison wherever possible to other leading technologies. We also provide proof-of-concept using a second Tag-Catcher system, that bivalent vaccines targeting two related pathogens, e.g. Ebola and Marburgh, can also be rapidly and easily generated. Once this platform technology is established, the universal VLP carrier will be available for display of antigens identified from future outbreak or emerging pathogens. Once the carrier platform is produced to cGMP, rapid vaccine production will simply rely on the expression of SpyTagged antigen relevant to the outbreak pathogen and rapid irreversible fusion to the VLP carrier. This technology platform will provide a rapid route to production of a final one-component VLP vaccine that is highly immunogenic and suited for single or repeated homologous immunisation.

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