

# disclosures

## *Director, Health Law Institute*

- Oversee a contract between HLI and Nova Scotia's Department of Health & Wellness
- HLI members provide time-limited confidential feedback to DHW on legislative and policy initiatives

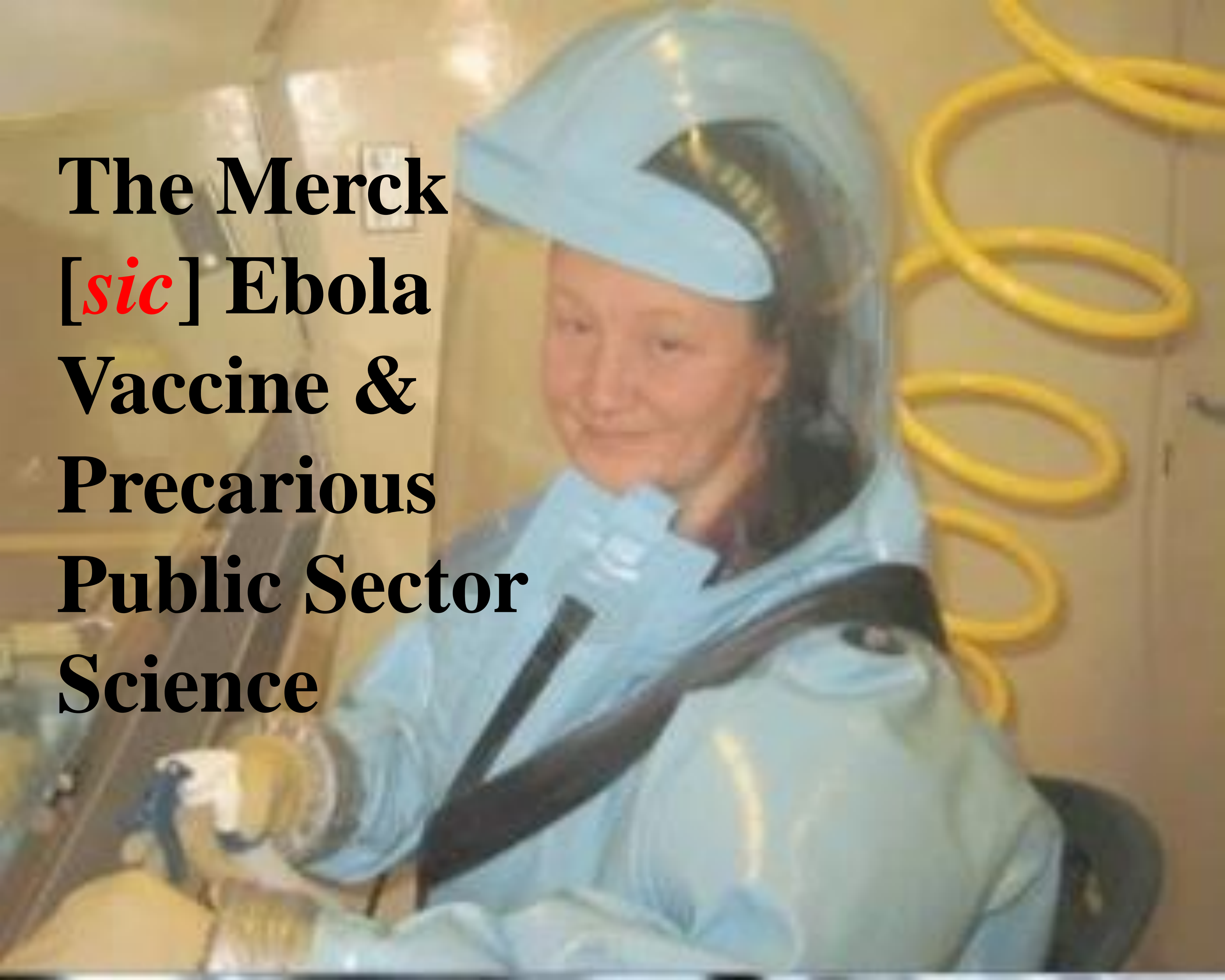
## *Member, Patented Medicine Prices Review Board*

- Paid honorarium (\$500) for each day of work for PMPRB
- Cannot work, consult, etc. with regulated industry
- Two roles:
  - 1) Policy development (e.g. PMPRB Guidelines);
  - 2) Decide merits of allegation of 'excessive pricing'

## *CIHR grants (EOG 123678, PJT 156256)*

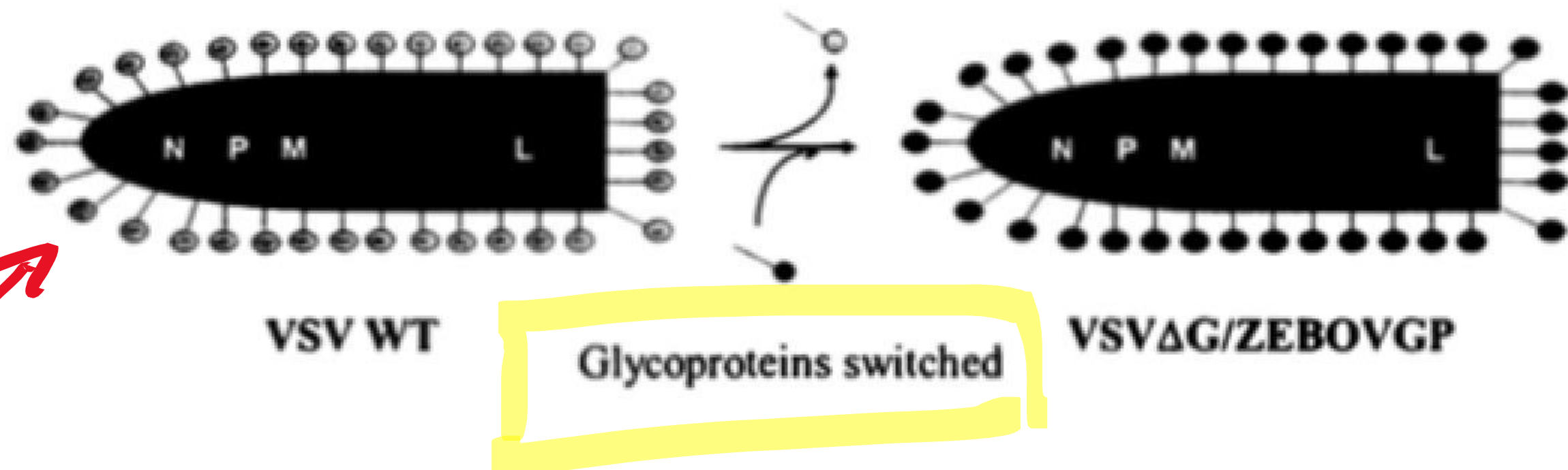
- Funding for research re: commercialization of research (EOG 123678) and improving transparency of pharmaceutical research and regulation (PJT 156256)
- Role: Nominated Principal Applicant for both
- CIHR has no role whatsoever in the design, conduct, or reporting of the research and its findings

**The Merck  
[*sic*] Ebola  
Vaccine &  
Precarious  
Public Sector  
Science**



rVSV-ZEBOV

**Figure 1:** Design of the VSV $\Delta$ G/ZEBOVGP vaccine. The glycoprotein gene from VSV was replaced with the glycoprotein gene from ZEBOV. This produced a recombinant VSV that had the same bullet structure as VSV but with the ZEBOV glycoprotein on the surface of the virus.







Public Health  
Agency of Canada

Agence de la santé  
publique du Canada

Access to Information and Privacy Division  
Division de l'accès à l'information et  
de la protection des renseignements personnels  
Holland Cross, Tour/Tower B, Suite 700  
1600 rue Scott Street  
AL: 3107A  
Ottawa, Ontario, K1A 0K9

*Your file Votre référence*

*Our file Notre référence*

**JAN 14 2015**

**A-2014-00102/kl2**

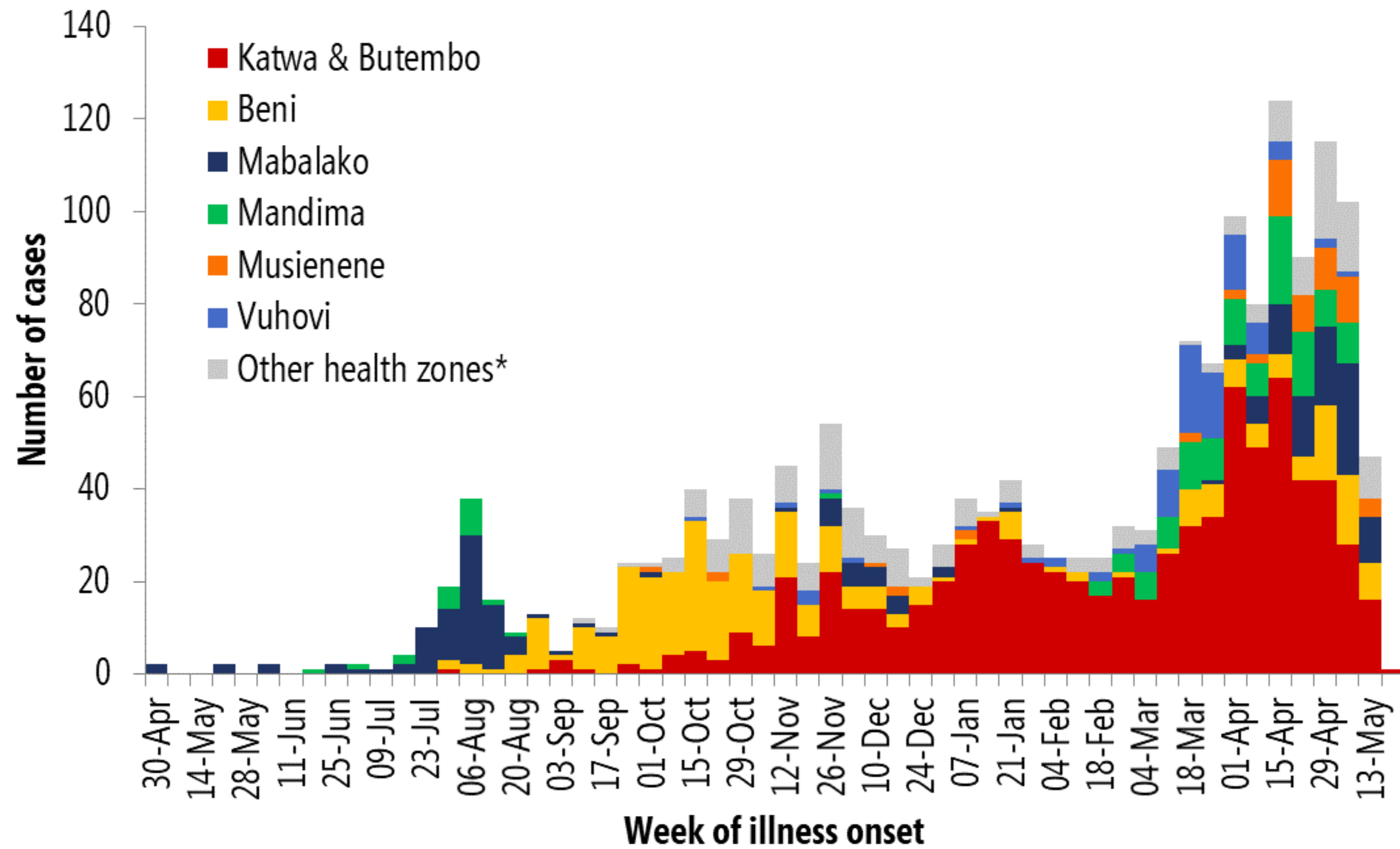
Matthew Herder, JSM, LL.M.  
Assistant Professor, Faculties of Medicine and Law  
Health Institute, Dalhousie University  
6061 University Avenue  
Post Office Box: 15000  
Halifax, Nova Scotia, B3H 4R2

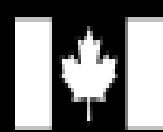
Dear Professor Herder,

This is further to your request submitted pursuant to the *Access to Information Act*, (the Act) as follows:

**"all records concerning any agreements or sub-agreements between the Government of Canada and any private sector company, including but not limited to Bioprotection Systems Corporation, in respect of all sole or other licences for recombinant vesicular stomatitis virus vaccines for viral hemorrhagic fevers, including in particular all studies, reports and related records arising from any agreements or sub-agreements in the period from 2000 to the present (December 24, 2014)."**







# Defence Research and Development Canada



Canada

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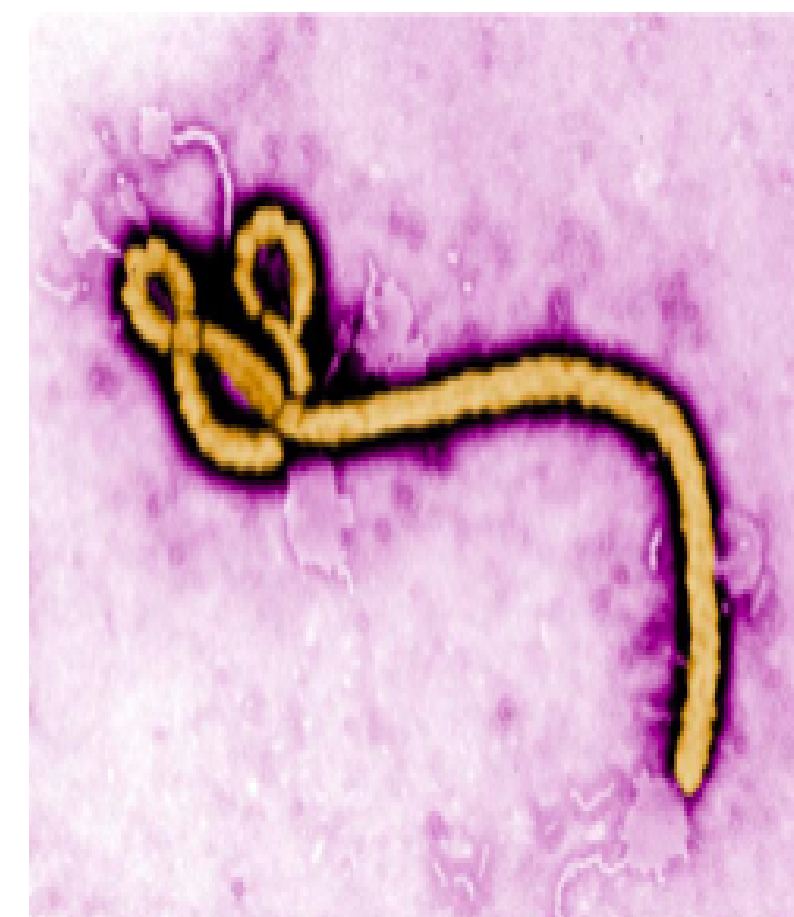
[DRDC Home](#) → [News](#) → News articles

## Foresight helped make Canada a world leader in Ebola research

September 10, 2014

The worst Ebola outbreak ever seen has struck a number of West African countries and infected thousands -- citizens, aid workers and health care personnel. Thousands have died. Although several solutions are in various stages of testing, no Ebola treatment or vaccine has yet been officially approved for human use.

There is hope as the medical community turns to experimental therapies, some of which were developed with support from the Chemical, Biological, Radiological-Nuclear (CBRN) Research and Technology Initiative (CRTI). The CRTI was a federal program led by Defence Research and Development Canada (DRDC), which has now been integrated as part of the Canadian Safety and Security Program (CSSP), also led by DRDC in partnership with Public Safety Canada.



Canadian scientists have developed antibodies that show great promise in treating Ebola.



## The “Canadian vaccine” fights Ebola

Researchers at the National Microbiology Laboratory developed both a vaccine to prevent the devastating Ebola virus and a drug to treat those already infected.

Led by Dr. Gary Kobinger, now director of the Centre de recherche en infectiologie at Laval University, the team developed the VSV-EBOV vaccine – known internationally as the “Canadian vaccine”– and the ZMapp treatment.



# The story of Canada's Ebola vaccine

Francis A. Plummer MD DrSc, Steven M. Jones PhD

■ Cite as: *CMAJ* 2017 October 30;189:E1326-7. doi: 10.1503/cmaj.170704

See related article at [www.cmaj.ca/lookup/doi/10.1503/cmaj.170074](http://www.cmaj.ca/lookup/doi/10.1503/cmaj.170074)

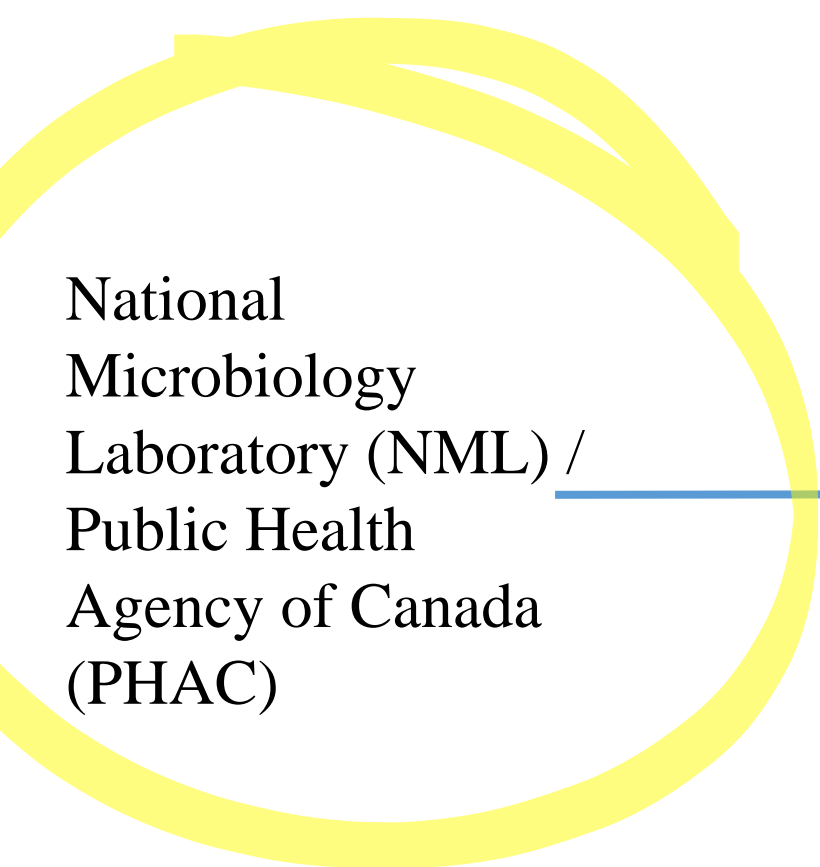
**T**he development of an effective Ebola vaccine by Canada's National Microbiology Laboratory is a great Canadian contribution to global public health. A linked study in *CMAJ* reports on a phase 1 trial of a recombinant vesicular stomatitis virus (VSV) Ebola vaccine developed in Canada.<sup>1</sup> This is the story of its development.

Ebola, a hemorrhagic fever filovirus, endemic in parts of Africa, was first recognized in 1976 in what is now the Democratic Republic of the Congo and first isolated at the Institute of

## KEY POINTS

- After the Ebola outbreak in West Africa in 2014–2015, a vaccine was quickly brought to clinical trial in the field.
- However, the development of an Ebola vaccine represents a great Canadian scientific effort and international collaboration that spanned almost two decades.
- The success of the vaccine may mean the end of Ebola virus infection as a global health threat.





National  
Microbiology  
Laboratory (NML) /  
Public Health  
Agency of Canada  
(PHAC)



Mar 2014:  
Ebola Outbreak Recognized by international community

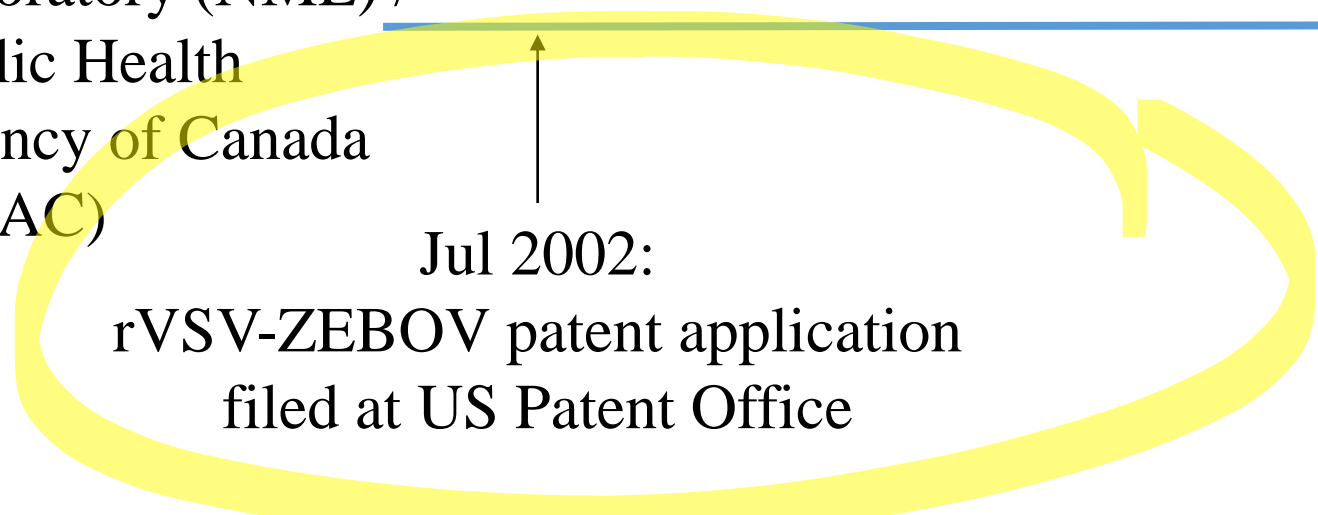


National  
Microbiology  
Laboratory (NML) /  
Public Health  
Agency of Canada  
(PHAC)

Jul 2002:

rVSV-ZEBOV patent application  
filed at US Patent Office

Mar 2014:  
Ebola Outbreak Recognized by international community





Mar 2014:  
Ebola Outbreak Recognized by international community

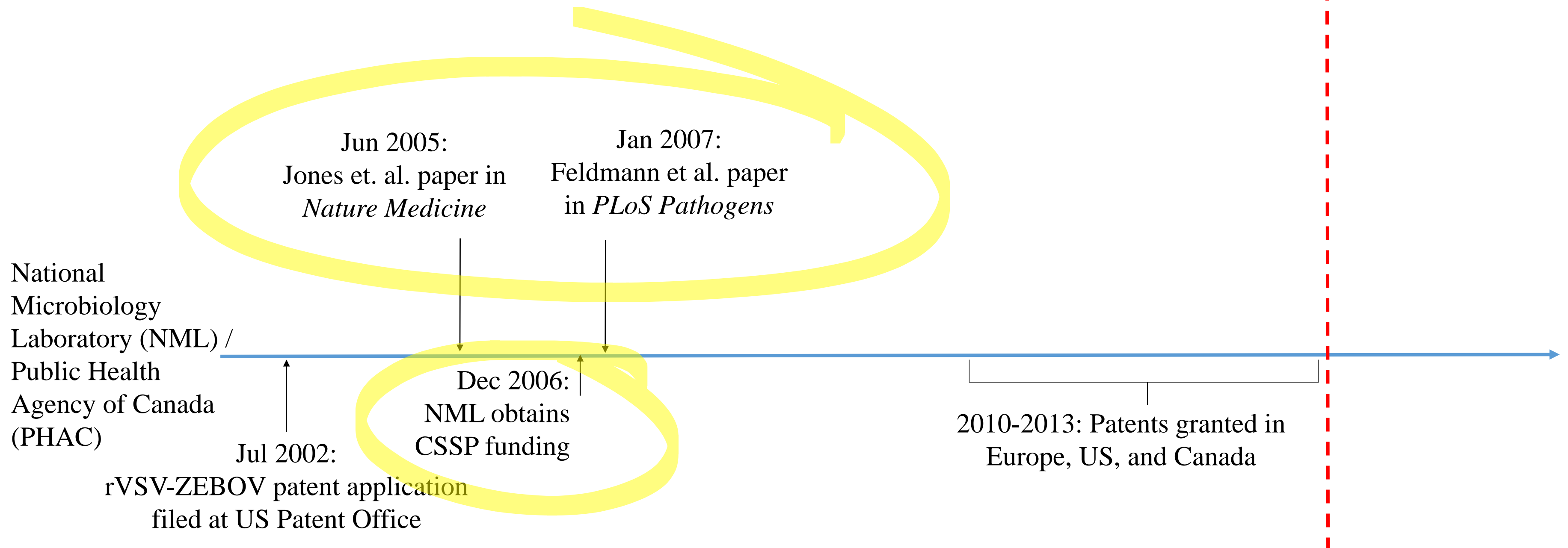
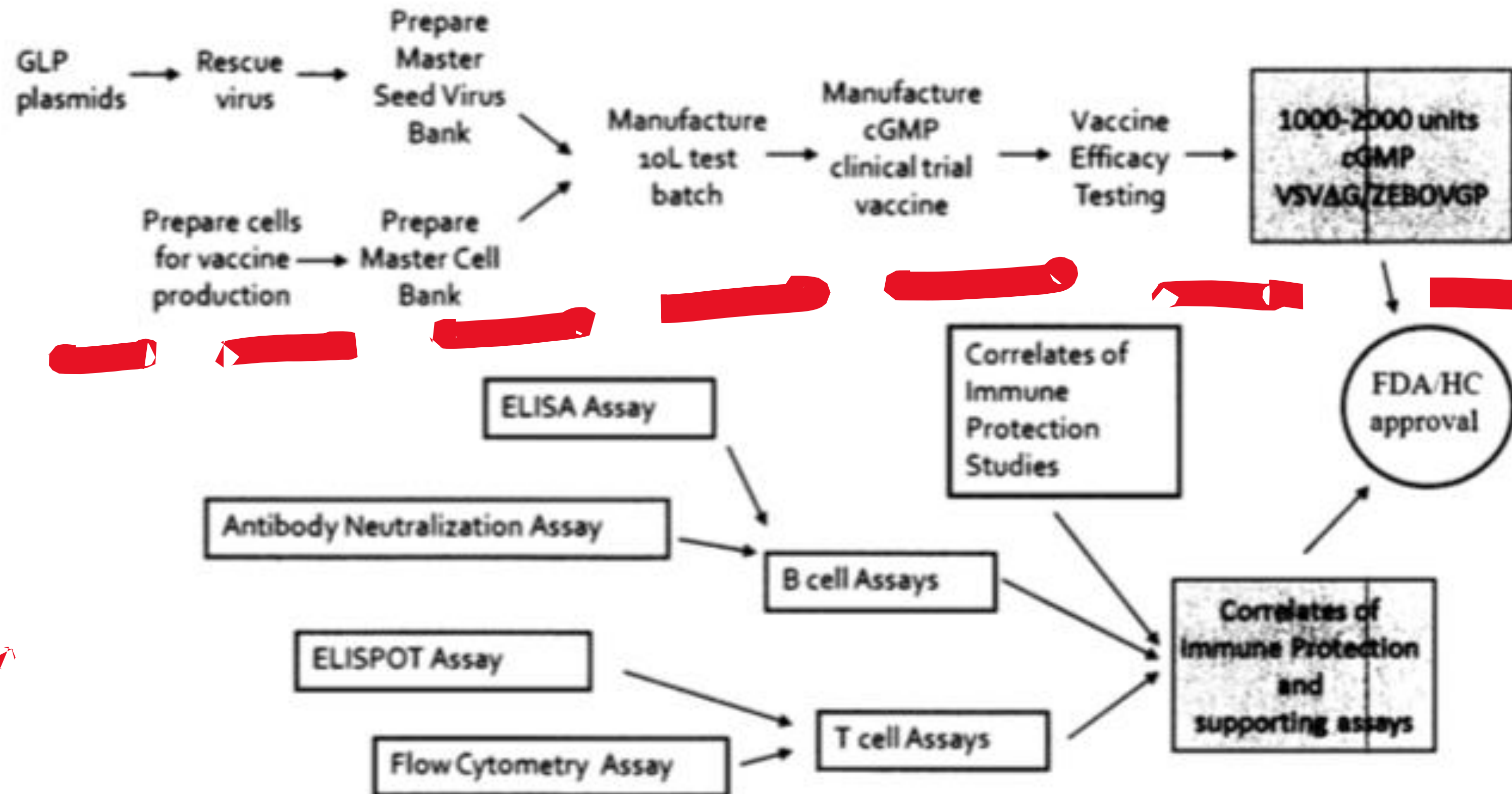
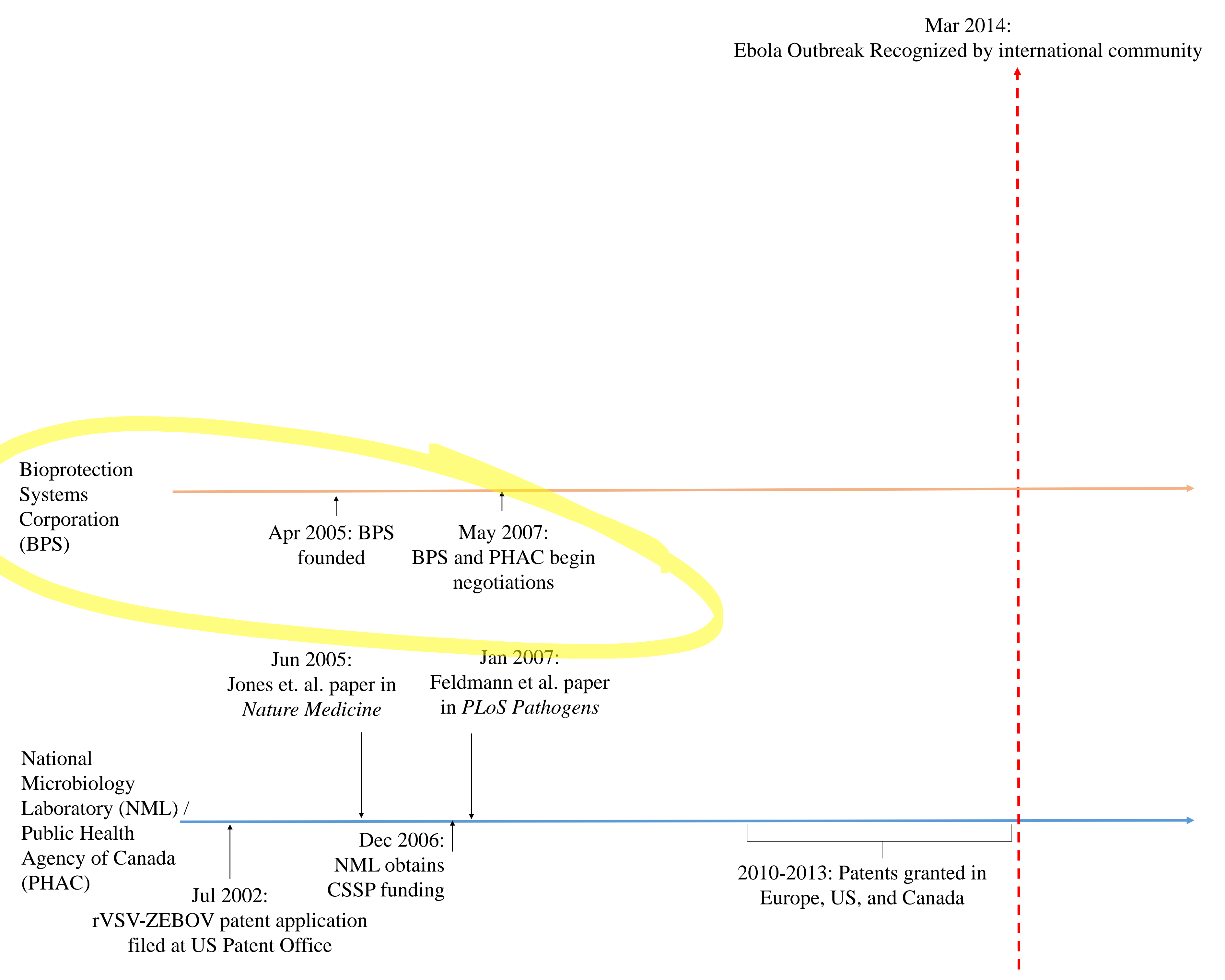


Figure #2: Overview of Project. There are two branches to the project, manufacturing, and research.







BPSC will strengthen the available research, efficacy and safety data with additional required studies to rapidly prepare and execute an IND and move the replication-competent VSV vaccine platform into phase I/II clinical trials.

***Objective #1: Preclinical vaccine testing***

We have the experienced regulatory, QA, QC and preclinical testing team efforts in place to complete all guarantee performance that meets the rigorous studies required by requirements of the FDA to submit for approval of an IND. Our team will work closely with PIAC's Special Pathogens program and combine their experience and expertise with ours.

***Objective #2: Safety and toxicology studies***

Our in-house experience and relationships with several CRO organizations that conduct pre-clinical testing will enable us to perform any additional studies that may be required by the FDA prior to the initiation of clinical trials with the envisioned rVSV-based vaccines.

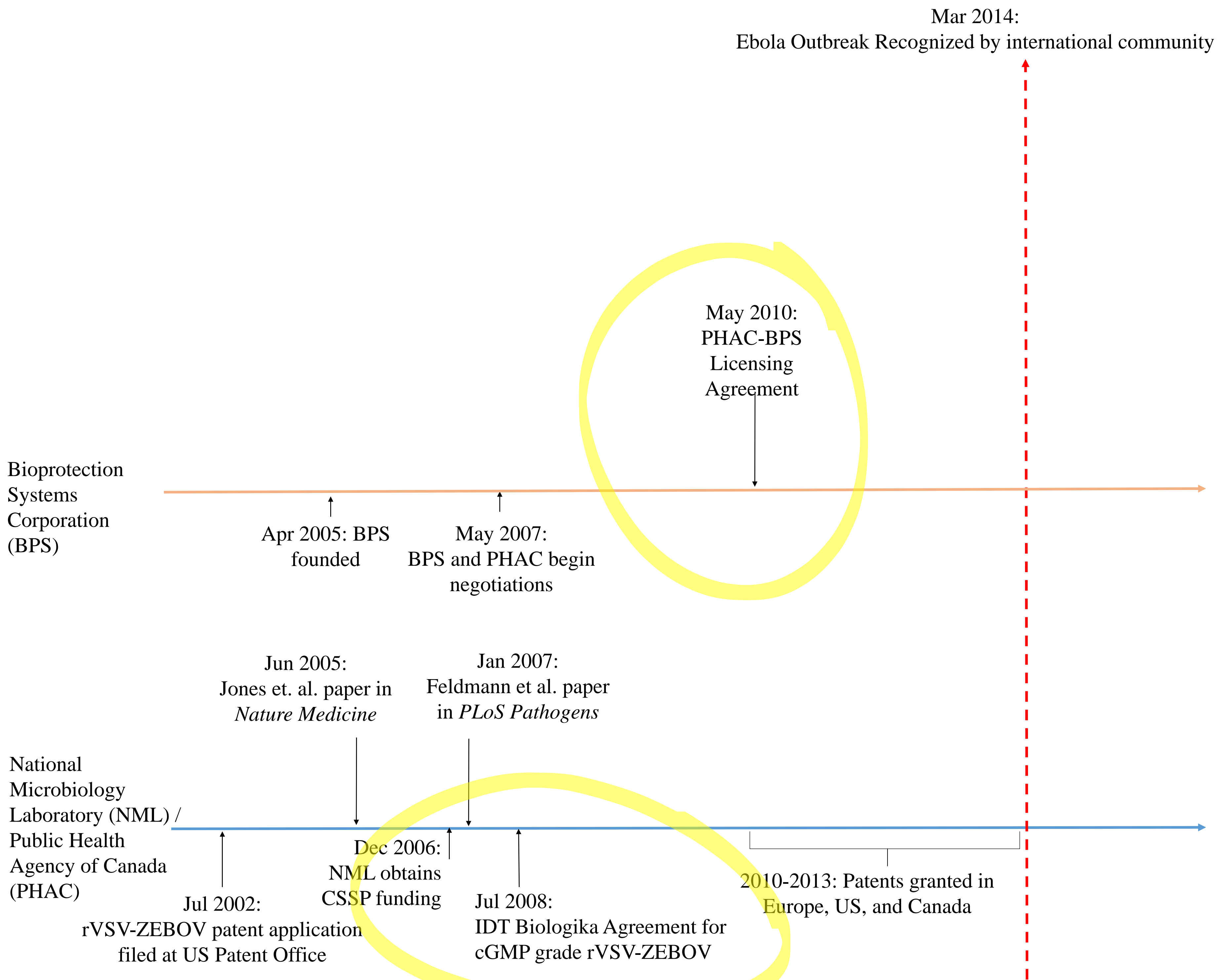
***Objective #3: Manufacturing of the vaccine***

We have the capacity and capability to manufacture the vaccine candidates under cGMP conditions at sufficient scale to allow completion of all preclinical and clinical testing. Furthermore, our well trained staff continues process development research to develop additional SOP's to monitor and improve production methods to optimize efficiency of vaccine manufacturing.

***Objective #4: Interactions with FDA and Clinical Testing***

We have the required teams and infrastructure (regulatory, medical, QA, QC) in place to complete this objective. In addition, we are in the process of implementing an electronic data capture system that is capable of highly efficient acquisition and management of all clinical data in a highly efficient manner. We believe the ability to perform these functions internally adds value to our company and should significantly accelerate product development and commercialization of this promising technology.





**Exhibit 10.67**

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

**SOLE LICENSE AGREEMENT  
FOR  
RECOMBINANT VESICULAR STOMATITIS VIRUS VACCINES FOR  
VIRAL HEMORRHAGIC FEVERS**

**BETWEEN:**

**HER MAJESTY THE QUEEN IN RIGHT OF CANADA,**

as represented by the Minister of Health,  
acting through the Public Health Agency of Canada

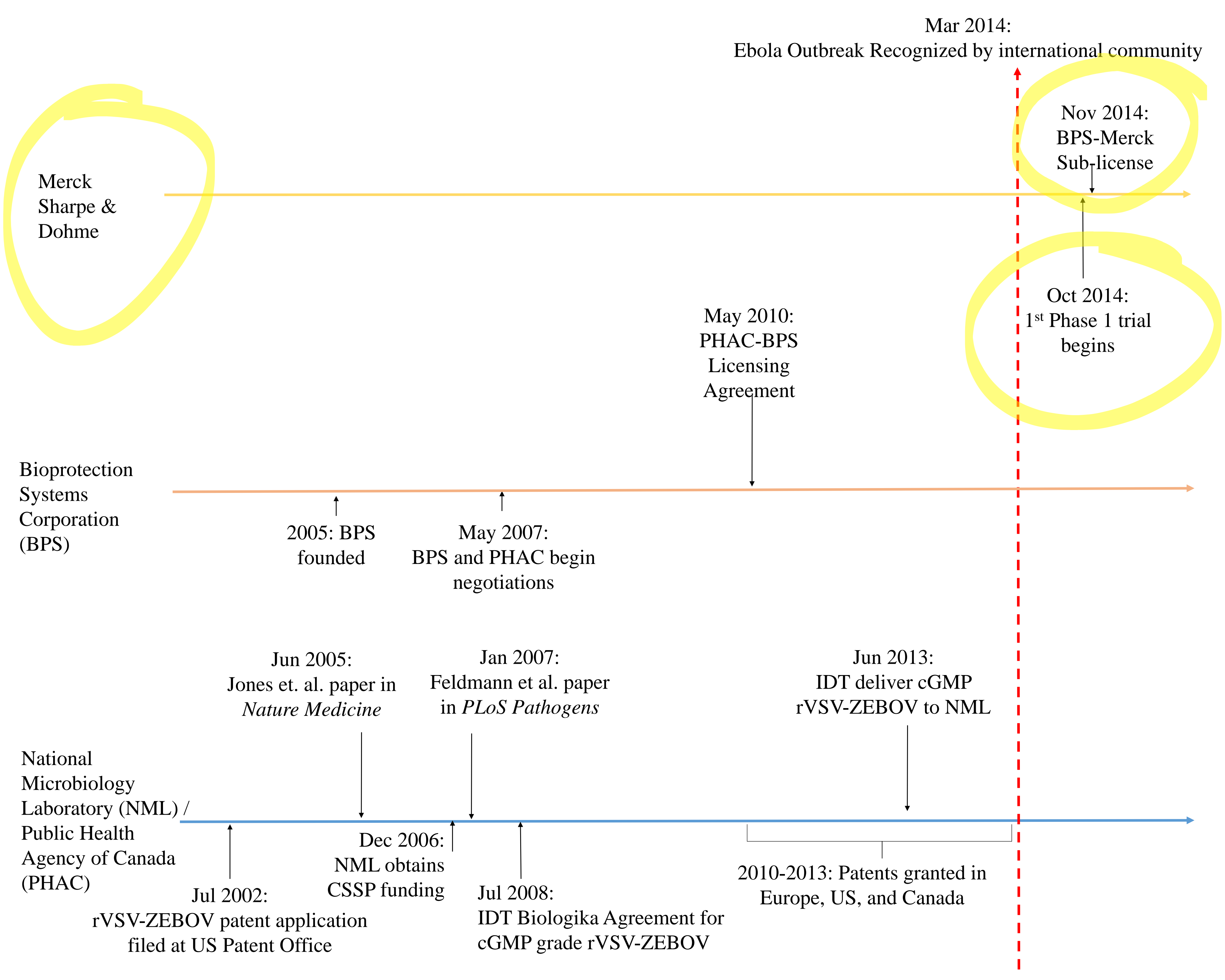
("Canada")

**AND:**

**BIOPROTECTION SYSTEMS CORPORATION,**

a company incorporated as a subchapter C corporation under the laws of Delaware,  
having its registered office at Iowa State University Research Park, 2901 South Loop





# Efficacy and effectiveness of an rVSV-vectored vaccine in preventing Ebola virus disease: final results from the Guinea ring vaccination, open-label, cluster-randomised trial (Ebola Ça Suffit!)



Ana Maria Henao-Restrepo, Anton Camacho, Ira M Longini, Conall H Watson, W John Edmunds, Matthias Egger, Miles W Carroll, Natalie E Dean, Ibrahima Diatta, Moussa Doumbia, Bertrand Draguez, Sophie Duraffour, Godwin Enwere, Rebecca Grais, Stephan Gunther, Pierre-Stéphane Gsell, Stefanie Hossmann, Sara Viksmoen Watle, Mandy Kader Kondé, Sakoba Kéita, Souleymane Kone, Eewa Kuisma, Myron M Levine, Sema Mandal, Thomas Mauget, Gunnstein Norheim, Ximena Riveros, Aboubacar Soumah, Sven Trelle, Andrea S Vicari, John-Arne Røttingen\*, Marie-Paule Kieny\*



## Summary

**Background** rVSV-ZEBOV is a recombinant, replication competent vesicular stomatitis virus-based candidate vaccine expressing a surface glycoprotein of Zaire Ebolavirus. We tested the effect of rVSV-ZEBOV in preventing Ebola virus disease in contacts and contacts of contacts of recently confirmed cases in Guinea, west Africa.

**Methods** We did an open-label, cluster-randomised ring vaccination trial (Ebola ça Suffit!) in the communities of Conakry and eight surrounding prefectures in the Basse-Guinée region of Guinea, and in Tomkolili and Bombali in Sierra Leone. We assessed the efficacy of a single intramuscular dose of rVSV-ZEBOV ( $2 \times 10^7$  plaque-forming units administered in the deltoid muscle) in the prevention of laboratory confirmed Ebola virus disease. After confirmation of a case of Ebola virus disease, we definitively enumerated on a list a ring (cluster) of all their contacts and contacts of contacts including named contacts and contacts of contacts who were absent at the time of the trial team visit. The

*Lancet* 2017; 389: 505–18

Published Online  
December 22, 2016  
[http://dx.doi.org/10.1016/S0140-6736\(16\)32621-6](http://dx.doi.org/10.1016/S0140-6736(16)32621-6)

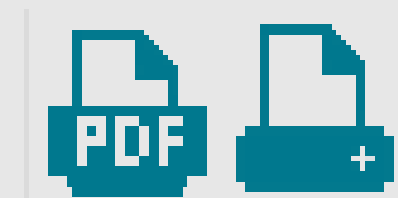
This online publication has been corrected. The first corrected version appeared at the lancet.com on December 23, 2016. The second corrected version appeared on February 2, 2017



# Merck Begins Rolling Submission of Licensure Application for V920 (rVSVΔG-ZEBOV-GP) to U.S. Food and Drug Administration

*V920 is the Company's Investigational Vaccine for Ebola Zaire*

Tuesday, November 13, 2018 4:35 pm EST



KENILWORTH, N.J.--([BUSINESS WIRE](#))--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that it has started the submission of a rolling Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for V920 (rVSVΔG-ZEBOV-GP, live attenuated), the company's investigational vaccine for Ebola Zaire disease. This rolling submission is made pursuant to the FDA's Breakthrough Therapy Designation for V920, which was announced by the company in July 2016.

"By the FDA agreeing to accept our BLA on a rolling basis, we have together made another important step forward in accelerating the regulatory review process for V920," said Paula Annunziato, M.D., vice president for clinical research, Merck Research Laboratories. "We are fully committed to the development of this important vaccine against Ebola. In the meantime, pre-licensure, investigational doses of V920 are available to support response to Ebola Zaire outbreaks on an emergency basis in coordination with global public health authorities."

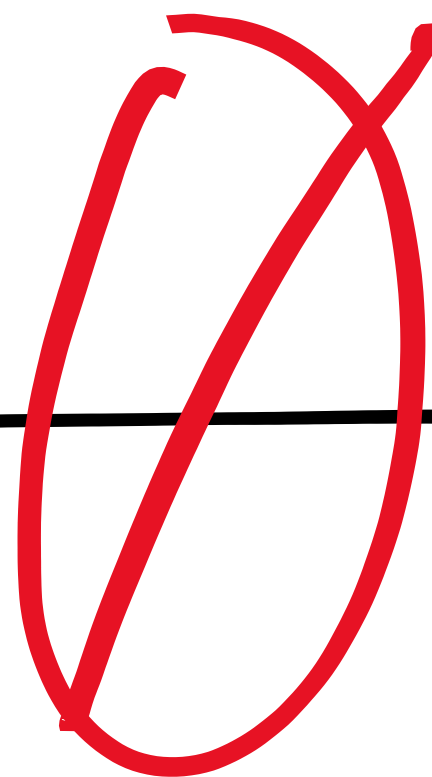
Currently, Merck expects the rolling submission of the BLA to be completed in 2019.

**success story ?**



May 2010

March 2014



BPSC will strengthen the available research, efficacy and safety data with additional required studies to rapidly prepare and execute an IND and move the replication-competent VSV vaccine platform into phase I/II clinical trials.

***Objective #1: Preclinical vaccine testing***

We have the experienced regulatory, QA, QC and preclinical testing team efforts in place to complete all guarantee performance that meets the rigorous studies required by requirements of the FDA to submit for approval of an IND. Our team will work closely with PIAC's Special Pathogens program and combine their experience and expertise with ours.

***Objective #2: Safety and toxicology studies***

Our in-house experience and relationships with several CRO organizations that conduct pre-clinical testing will enable us to perform any additional studies that may be required by the FDA prior to the initiation of clinical trials with the envisioned rVSV-based vaccines.

***Objective #3: Manufacturing of the vaccine***

We have the capacity and capability to manufacture the vaccine candidates under cGMP conditions at sufficient scale to allow completion of all preclinical and clinical testing. Furthermore, our well trained staff continues process development research to develop additional SOP's to monitor and improve production methods to optimize efficiency of vaccine manufacturing.

***Objective #4: Interactions with FDA and Clinical Testing***

We have the required teams and infrastructure (regulatory, medical, QA, QC) in place to complete this objective. In addition, we are in the process of implementing an electronic data capture system that is capable of highly efficient acquisition and management of all clinical data in a highly efficient manner. We believe the ability to perform these functions internally adds value to our company and should significantly accelerate product development and commercialization of this promising technology.



USD \$50M



Exhibit 10.105

EXECUTION COPY

## LICENSE AND COLLABORATION AGREEMENT

This License and Collaboration Agreement (this “**Agreement**”) is effective as of November 21, 2014 (the “**Effective Date**”), and is entered into by and between **MERCK SHARP & DOHME CORP.**, a corporation organized and existing under the laws of New Jersey (“**Merck**”), and **BIOPROTECTION SYSTEMS CORPORATION**, a corporation organized and existing under the laws of Delaware (“**NewLink**”) and a wholly owned subsidiary of **NEWLINK GENETICS CORPORATION**, a corporation organized and existing under the laws of Delaware (“**NL**”), and for purposes of Section 10.19, NL.

### RECITALS:

**WHEREAS**, NewLink is currently developing a rVSV-EBOV (Ebola) vaccine; and

**WHEREAS**, NewLink and Merck desire to enter into a collaboration in order to research, develop, manufacture and commercialize Compounds (as hereinafter defined) and Products (as hereinafter defined), upon the terms and conditions set forth herein; and

**WHEREAS**, NewLink desires to grant to Merck licenses under the NewLink Patent Rights (as hereinafter defined) and NewLink Know-How (as hereinafter defined) to research, develop, manufacture and commercialize Compounds and Products upon the terms and conditions set forth herein.

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency of which are hereby acknowledged, Merck and NewLink hereby agree as follows:

**Table 1.** Funding received by BioProtection Systems Inc. 2008-2016 in USD\$.

Fiscal Year	Dept. of Health & Human Services	Dept. of Defense	Dept. of Agriculture	Total	Pre- & Post-Epidemic Total
2008	462,742	69,990	-	532,732	\$9,688,115 (2008-2013)
2009	43,062 535,681	630,738 29,995 3,707,837	-	4,947,313	
2010	299,975	119,261	-	419,236	
2011	299,920	3,388,914	100,000	3,788,834	
2012	-	-	-	-	
2013	-	-	-	-	\$119,355,036 (2014-2016)
2014	-	1,000,000 1,885,871 (738)	-	2,885,133	
2015	29,967,985 17,883,564 4,467,990	1,025,080 8,168,814 1,504,482 961,958	(10,000)	63,969,873	
2016	24,752,733 2,227,245 593,685 21,681,676	2,794,840 534,323 (15,458) (69,013)	-	52,500,031	
<b>Total</b>	\$103,216,258	\$25,736,893	\$90,000	\$129,043,151	

pre-

post-



### **Acknowledgments**

We thank the people in Basse-Guinée for their participation, and the entire field, laboratory, and data management staff who worked tirelessly and in difficult conditions to successfully implement this trial.

Merck Sharp & Dohme provided the vaccine used in the trial. We would like to acknowledge the support of the following organisations:

Wellcome Trust, the UK Government through the Department of International Development, Guinean Ministry of Health, Norwegian Ministry of Foreign Affairs, US Department of Defence, Public Health Agency of Canada, Swiss Agency for Therapeutic Products, the Bill & Melinda Gates Foundation, Health Canada, the VSV Ebola Consortium (VEBCON), and the European Commission. We also thank Donald A Henderson\*, Jeremy Farrar, Richard Peto, Tore Godal, Bruce Aylward, Djilali Abdelghafour, Oumou Bah Sow, Mohammed Belhocine, Pierre-Henri Bertoye, Yap Boum, Mar Cabeza-Cabrerizo, Rokiatu Dembele, Laura De Paoli, Aboubacar Sidiki Diakité, Ahmadou Diallo, Mamoudou Harouna Djingarey, Julia Djonova, Pascal Frison, Melba Filimina Gomes, Myriam Grubo, Yper Hall, Raul David Hone, Raul Iraheta, Olivier Lapujade, Murray Lumpkin, Christine Maure, Corinne Merle, Nicholas Misso, Jérôme Mouton, Pierre Ndiaye, Bjørg Dystvold Nilsson, Marie-Pierre Preziosi, Vasee Moorthy, Jean-Marie Okwo-Bele, William Perea, Guenal Rodier, Maria Magdalena Guraib, Martina Rothenbühler, Abha Saxena,

Identifier	Sponsor(s)	Collaborator(s)	Phase	Start Date	Completion Date	#Participants
NCT02269423	Merck Sharp & Dohme Corp.	BioProtection Systems Corporation United States Department of Defense	1	Oct. 2014	Aug. 2015	39
NCT02280408	Merck Sharp & Dohme Corp.	National Institute of Allergy and Infectious Diseases (NIAID) BioProtection Systems Corporation	1	Oct. 2014	Dec. 2015	39
NCT02374385	Dalhousie University	Canadian Institutes of Health Research (CIHR) NewLink Genetics Corporation	1	Nov. 2014	Jun. 2015	40
NCT02283099	Universitätsklinikum Hamburg-Eppendorf	German Center for Infection Research Philipps University Marburg Medical Center World Health Organization Clinical Trial Center North University Hospital, Geneva Albert Schweitzer Hospital Institute of Tropical Medicine, University of Tuebingen Wellcome Trust KEMRI-Wellcome Trust Collaborative Research Program	1	Nov. 2014	Nov. 2015	30
NCT02287480	University Hospital, Geneva	World Health Organization Wellcome Trust Universitätsklinikum Hamburg-Eppendorf Philipps University Marburg Medical Center Albert Schweitzer Hospital Institute of Tropical Medicine, University of Tuebingen KEMRI-Wellcome Trust Collaborative Research Program	1	Nov. 2014	Jan. 2016	115
NCT02296983	University of Oxford	World Health Organization Wellcome Trust Institute of Tropical Medicine, University of Tuebingen Albert Schweitzer Hospital Philipps University Marburg Medical Center Universitätsklinikum Hamburg-Eppendorf University Hospital, Geneva	1	Dec. 2014	Sep. 2016	40*
NCT02314923	Merck Sharp & Dohme Corp.	BioProtection Systems Corporation US Department of Health and Human Services	1	Dec. 2014	Jun. 2016	512
NCT02344407 “PREVAIL”	National Institute of Allergy and Infectious Diseases (NIAID)	None	2	Jan. 20, 2015	Jun. 1, 2020*	1500*
PACTR201503001057193 “Ebola ca suffit!”	World Health Organization	Ministry of Health Guinea Medecins Sans Frontieres Epicentre Norwegian Institute of Public Health Institute of social and preventive medicine and centre for clinical trials University of Bern London School of Hygiene and Tropical Medicine University of Florida Centre for Vaccine Development, Mali/Maryland Public Health England Public Health Agency of Canada NewLink/Merck	3	Mar. 3, 2015	Jan. 20, 2016	8851
NCT02378753 “STRIVE”	Centers for Disease Control and Prevention	University of Sierra Leone Ministry of Health and Sanitation, Sierra Leone Department of Health and Human Services eHealth Africa	2/3	Apr. 2015	Dec. 5, 2016	8651
NCT02503202	Merck Sharp & Dohme Corp.	None	3	Aug. 17, 2015	Sep. 29, 2017*	1198
NCT02933931	University Hospital, Geneva	None	1	Nov. 2016	Apr. 2020*	100*
NCT02876328	National Institute of Allergy and Infectious Diseases (NIAID)	The Liberia-US Clinical Trials Partnership Program, Partnership for Research on Ebola Virus in Liberia Project (PREVAIL) Institut National de la Santé Et de la Recherche Médicale, France London School of Hygiene and Tropical Medicine	2	Mar. 31, 2017	Mar. 2019*	5500*

**power of public sector science**



## En science les silent

zling of scientists, Harper's  
controlling the message verges  
ian. By Jonathon Gatehouse

[illegible]

masked federal scientists and suppressed research that are being brought to the union's attention, he says. All against the backdrop of sweeping cuts to water, air and wildlife monitoring programs, a total restructuring of federal environmental reviews, and the downloading of responsibility for lakes and rivers to the provinces. "It's almost like this government doesn't want any of this stuff to be open to public discussion," says the union leader. "What we're seeing is a total lockdown."

Since taking power in 2006, Stephen Harper's government has rarely been caught on the wrong foot. Disciplined on the hearings, in the House, and above all with the media, Tory ministers and MPs have largely avoided the gaffes and unvarnished opinions that used to plague the conservative movement. But in many of its critics, Ottawa's obsession with controlling the message has become an all-encompassing that is now threatening both the health of Canada's democracy and the country's reputation abroad.

And the principal battleground—where the micromanaging impulse seems to have taken on a zeal fuelled by ideological distrust—is the environment. Since Harper pulled out of the Kyoto Protocol, citing skepticism about the cost and efficacy of international efforts to halt climate change (and saving the country as much as \$14 billion in penalties for non-compliance) his government has been stuck with an unenviable sales job: trying to promote the expansion of Alberta's oil sands—a significant driver of the national economy—while downplaying the sector's rapidly growing greenhouse gas emissions and the government's own inactivity. One strategy was to brand the business as an "ethical" alternative to oil from

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interrupt or repressive regimes in the Middle East and elsewhere. Another way to go on the attack. Environmental groups opposing pipeline plans have been denounced as "radicals," accused of taking funding from "foreign special interests" and subject to special audits regarding their charitable status from the Canada Revenue Agency. And just this past week, Natural Resources Minister Joe Oliver picked a fight with NASA's James Hansen, accusing the recently retired climate scientist of "crying wolf all the time" and exaggerating the oil sands' contribution to global warming.

Neither approach has borne much fruit. The proposed Keystone XL pipeline, which would

pump Canadian crude to refineries along the Texas Gulf coast, remains mired in the U.S. approval process, while activists and even some policy-makers make it the focal point of their fight against "dirty oil." Meanwhile Canada's global reputation on green issues has taken a beating. (A January 2003 report (and an international environmental performance based on indicators like air quality and biodiversity) ranked Canada 27th among the world's 17 most developed nations.) And all these audits—almost 300, at a cost of \$1 million—resulted in just one group, Physicians for Global Survival, losing their tax-deductible status for exceeding the limits on political spending.

But if Ottawa hasn't found a way to manage the activists or foreign public opinion, it's shown remarkable resolve—and success—in denying its opponents federally funded ammunition. According to internal Environment Canada documents, obtained by Climate Change Network Canada via Access to Information, the amount of ammunition the media paid to federal climate-change research dropped precipitously—80 per cent fewer stories—once the procedures for gaining access to government scientists were tightened during Harper's first mandate. In the first nine months of 2008, for example, the department's four leading researchers were quoted

**Caption:** *Navigation being allowed by the government resumed in Dili on 10 April 13*

in a total of 11 newspaper stories, versus 99 over the same period the year before.

Meanwhile, the list of cases where government scientists have been effectively gagged from speaking about peer-reviewed research—sometimes even after its publication in prestigious international journals—grows.

\* David Suzuki, an Environment Canada scientist, was prevented from doing interviews about a *Nature* paper on an unprecedented hole in the ozone layer over the Arctic in the fall of 2011. Reporters were instead





~~Feldmann~~

~~Jones~~

~~Stroher~~





**Pushed IDT to stay on schedule**

Gesendet: Montag, 26. November 2012 19:47

An: [REDACTED]

Betreff: teleconference

H [REDACTED]

I have emailed [REDACTED] and [REDACTED] about having a teleconference this week. As [REDACTED] is away until Dec 3 her email says I should contact you. I have concerns about the current VSVZEBOV production run and I want to discuss it sooner rather than later. Below is the email that I sent to them.

I haven't heard from you about when a good date and time would be for a teleconference regarding the current VSVZEBOV production. I still have concerns regarding the delay in downstream processing and bottling. I still don't agree with the January bottling date as it is keeping the product at 4C for too long. Additionally, it is cutting the QC short as well. I think this could have a potential negative impact on the final product and I would like to discuss it with you. Because we are running short on time until the deliverable date I also wanted to discuss any possible backup plans in case this production run fails. I would like [REDACTED] to participate in the discussion as it will impact the timeline of his future studies.

I am available on November 28 and 29 beginning from 8 am and later Winnipeg time. Let me know what works for you.

Judie Alimonti, Ph.D.  
Special Pathogens Program  
Public Health Agency of Canada  
1015 Arlington St  
Winnipeg, Manitoba, Canada  
R3E 3R2  
Office Ph: 204-784-5998  
Lab Ph: 204-789-5097  
Fax: 204-789-2140

**Coordinated BPS/IDT/FDA**



Here are some of the questions that [REDACTED] wants us to ask the FDA. Her biggest concern is the testing strategy for the AA testing. We are going to use the virus removed vaccine for the in vivo tests on the MSV and the cGMP batch. So these assays are using the normal protocol. However, based on her comment below it looks like she is asking if the in vivo tests are sufficient ??? and that the in vitro tests are unnecessary. However, I know she had suggested in another email to do PCR for the in vitro tests. So perhaps these questions could be phrased appropriately to the FDA. I think she also wants to know what other agents need to be tested in addition to the usual adventitious agents that they test for. Please see her comments below.

In regard to testing strategy ... This is something which must be discussed with the FDA ... we need to ask the right question to get confirmation the following strategy:

1. We need confirmation of the MCB testing ... according to the COA we should have sufficient testing for Phase I/II ... EOP testing will be for later clinical phase
2. We need confirmation on the human and simian testing PCR of the MCB
3. We will test the MSV with the same human and simian PCR as the MCB. For AA we will only do the test in vivo (guinea pigs, mice, suckling mice (virus reduction required) and no in vitro assay. But will offer the strategy for virus neutralisation for later clinical phase studies
4. For the CMT we have a complete serum free process, we will only do the AA in vivo and no AA and no in vitro testing with the same argue as for the MSV.

Please talk to [REDACTED] and [REDACTED] prior your Pre-IND

I am providing you the manufacturing summary as an attachment. [REDACTED] also sent along some information regarding the removal of the virus from the vaccine. I think there were some questions there for the FDA as well.

I am supposed to receive the other document you requested in a day or two.





Re: AW: SOp numbers purity /ID [redacted]

Judie Alimonti to [redacted]

2012-11-07 03:06 PM

H [redacted]

I have confirmed with [redacted] (from his contact with the FDA) the following PCR AA testing that needs to be performed on the MSV.

AA testing to keep

1x: Detection of 9CFR Bovine Viruses

1x: Quantification Of Reverse Transcriptase Activity By Ultracentrifugation And  
Quantitative Fluorescent Product Enhanced Reverse Transcriptase (QFPERT) Assay

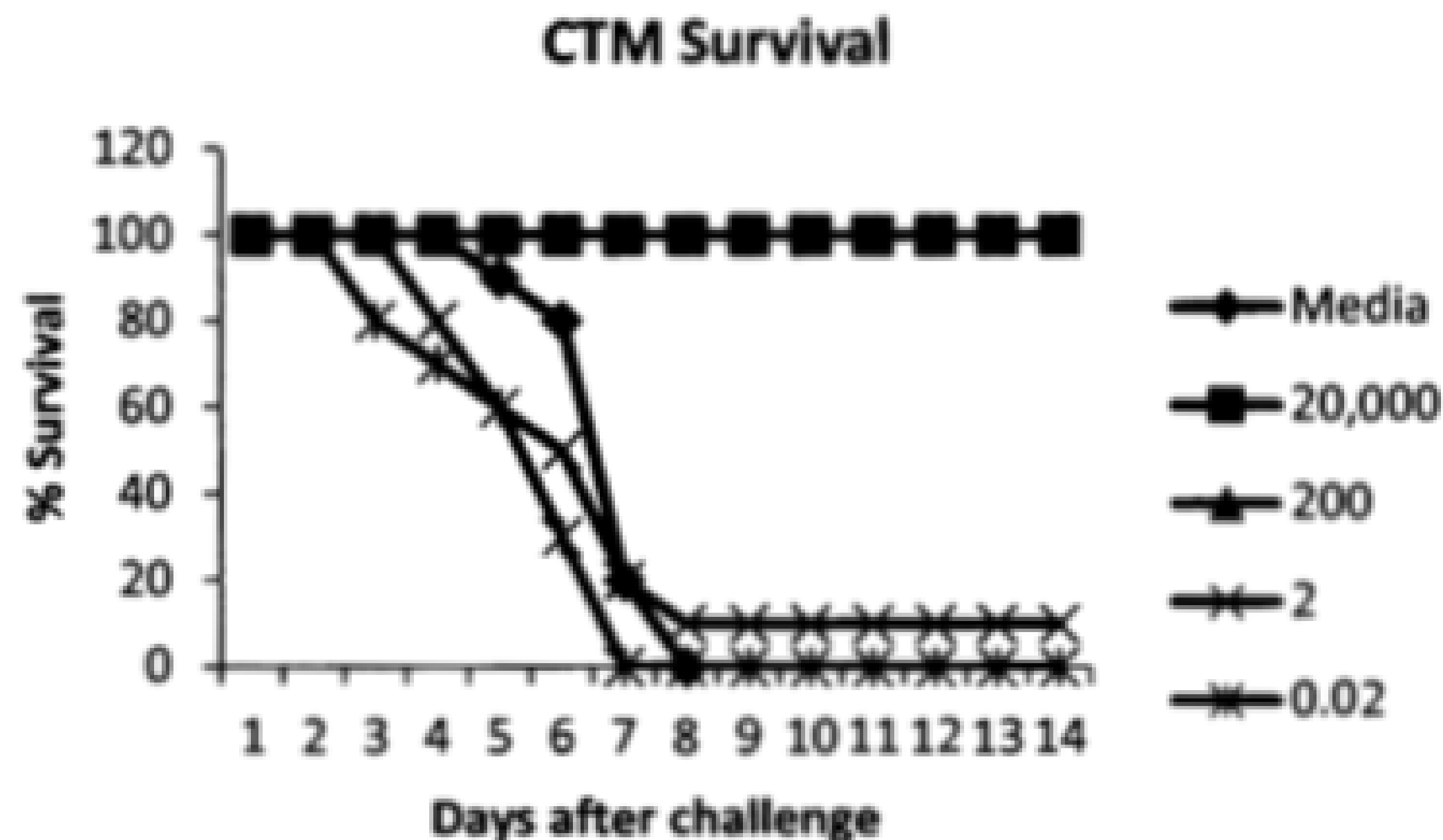
1x: Real time-PCR for the Detection of Human Viruses (FDA PTC and CPMP) +  
Hepatitis A and B19

1x: Real time-PCR Detection of Porcine Parvovirus

**Performed key efficacy  
experiments**



**Figure 3. Efficacy testing of the CTM in mice.** Mice were vaccinated with varying doses (plaque forming units) of either the CTM or R&D VSV $\Delta$ G/EBOVGP. The mice were then challenged 28 days later with a uniformly lethal dose (1000 LD<sub>50</sub>) of mouse adapted ebola (MA-EBOV). The survival of the mice at the various doses is shown for the CTM and is compared to the R&D vaccine. The CTM is effective but less potent than the R&D vaccine.



Hi [REDACTED]

We will be doing the tests and not BPS. Once we have the information I will send it to you.

Judie Alimonti, Ph.D.

Special Pathogens Program

Public Health Agency of Canada

1015 Arlington St

Winnipeg, Manitoba, Canada

R3E 3R2

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Fax: 204-789-2140

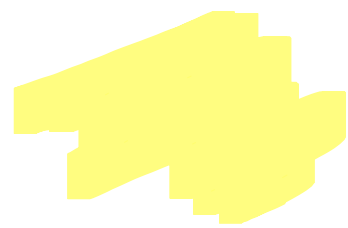
[REDACTED]

[REDACTED]

[REDACTED]

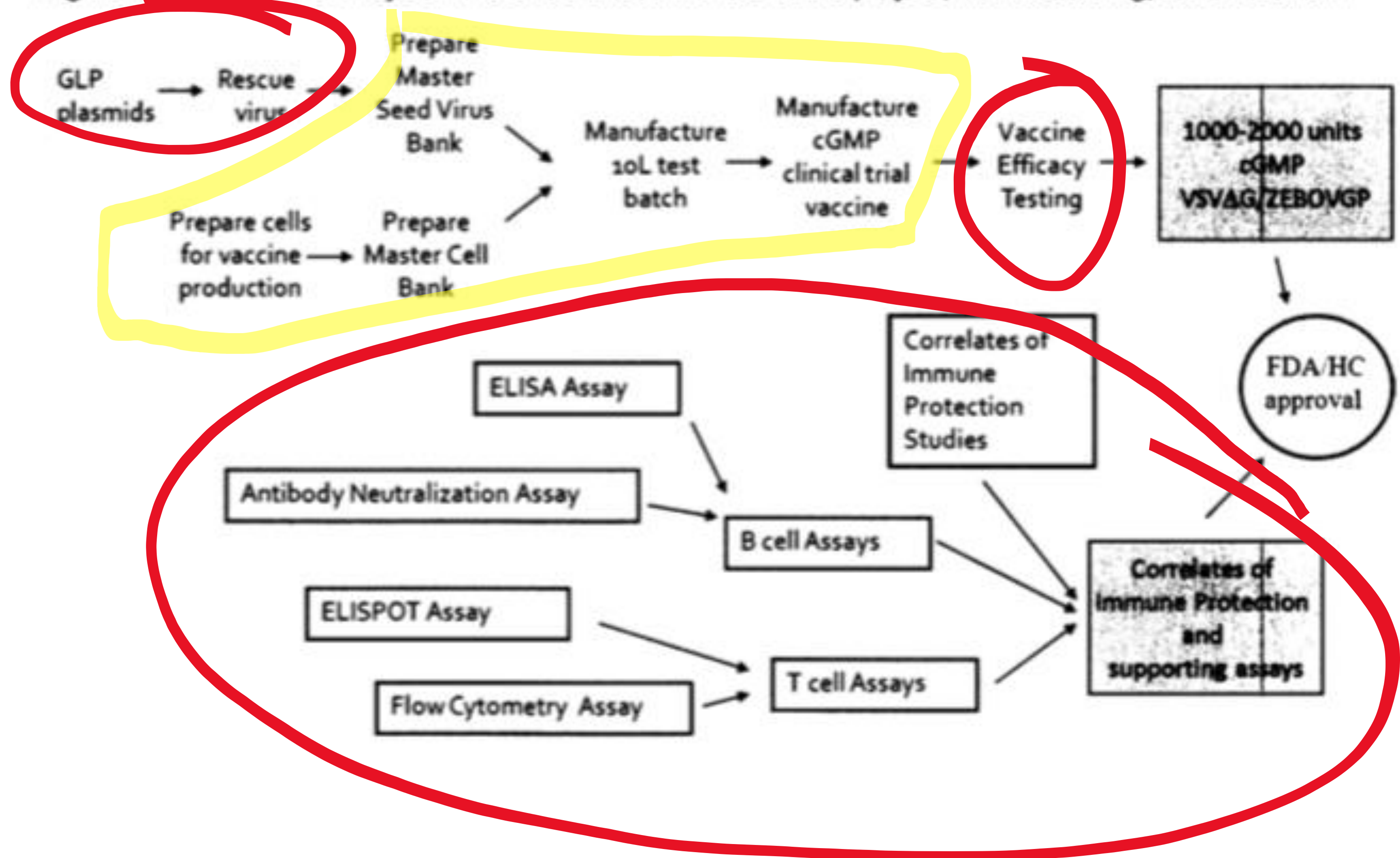


- NML



- NML + IDT

Figure #2: Overview of Project. There are two branches to the project, manufacturing, and research.





# Exclusive: Canada to donate its own Ebola vaccine to WHO for use in Africa

Rod Nickel

4 MIN READ



WINNIPEG Manitoba (Reuters) - Canada will donate a small quantity of an experimental Ebola vaccine developed in its government lab to the World Health Organization for use in Africa, the country's health minister said on Tuesday.





HEALTH

# WHO readies to test Merck's experimental Ebola vaccine in Congo outbreak

By HELEN BRANSWELL @HelenBranswell / MAY 11, 2018





