MEETINGS WITH
AND

Visit to World Economic Forum, Davos

Friday, 23 January 2015 - 11:30-12:00

Venue: In front of Bilateral PL13

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Key messages

- Confirm the Commissions continued support to Ebola research also in the post Ebola phase and congratulate the success of Johnson & Johnson and the London School of Hygiene and Tropical Medicine in the IMI 'Ebola+' call.
- Inform about the retirement of the current director of EDCTP and enquire for suggestions for his replacement.
- Inform about the DG RTD conference on "Maternal and Child Health – the role of research and innovation" to be held this year in July or October, and invite them to be involved in the event.

1. STEERING BRIEF

1.1 Scene setter

This is a courtesy meeting between you, [Name] and [Name], and will allow you to follow up on previous discussions. You met with [Name] and [Name] in the frame of the EDCTP2 launch event in Cape Town where they were among the invited leaders in global health research at the lunch meeting hosted by you.

[Name] is the Head of Maternal Health at the London School of Hygiene and Tropical Medicine (LSHTM, a global top 5 institute for tropical medicine).

[Name] held his current position for 3 years and was formerly the Global Principal Investigator for the Malaria initiative of the Gates Foundation.

LSHTM involvement in recent IMI Ebola+ call:
EBOVAC1 (coordinator): Development (phase 1 and 3) of J&J vaccine candidate.
EBOVAC2 (partner): Development (Phase 2) of the J&J vaccine candidate.
(The J&J vaccine candidate development project had to be split into two projects so that the two major research institutes, LSHTM-UK and INSERM-France, could both be allowed to coordinate a part of the project.)
EBODAC (coordinator): Ensuring compliance with Ebola vaccine regimens.

These three projects have been awarded a total of €154 million from IMI, with an EC contribution of €101 million, and an in-kind contribution by J&J of €53 million. Additionally, the LSHTM is a partner in the Ebola Tx project, recently funded from H2020 through the fast-track procedure with €2.9 million. This project has already started studying plasma from Ebola survivors as a potential treatment.

is a subsidiary of Johnson and Johnson (J&J) of J&J. J&J is strongly engaged in global health, in particular on HIV/AIDS and Hepatitis C drugs and anti-infectives.

J&J committed to contribute towards eliminating or controlling 10 neglected tropical diseases by 2020, by signing in 2012 the so-called London Declaration together with other major pharmaceutical companies, such as AstraZeneca, Bayer, GlaxoSmithKline, Merck KgaA, MSD, Novartis, Pfizer, Sanofi (see Annex 5.6).

J&J has a vaccine candidate against Ebola under development and will be awarded (together with academic non-industry partners) 4 research grants for its development following the first IMI Ebola+ call launched on 6 November 2014 and the evaluation results announced on 16 January. J&J participates in these 4 projects with a total in-kind contribution of €89.6 million and an EC contribution of €102.4 million. Out of these 4 projects with J&J participation, LSHTM is involved in two as coordinator and one as participant (see list above). The other project with J&J participation is EBOMAN on J&J vaccine up-scaling of production. Further details on the IMI Ebola+ call are attached in the Annex 5.2.

When organising the meeting indicated that wished to thank you for the very important commitment of the European Commission to Ebola, and that is looking forward to the signing of the grant agreements of the IMI Ebola+ call.

After recent reports of a seemingly better than projected control of the outbreak, there is growing concern that many planned clinical trials on vaccines and treatments will struggle to complete their studies before the outbreak ends. This is especially relevant to the J&J vaccine candidate, as it will be entering clinical trials quite late in the course of the outbreak.

1.2 Objectives

Discuss research on the Ebola outbreak, and get their views on the post-Ebola research strategy.

Enquire about J&J’s plans to engage in the development of drugs and vaccines on other neglected infectious and parasitic diseases of poverty in particular in the context of EDCTP2.
Enquire their opinion and advice about a DG RTD event within the framework of the European Year for Development on "Maternal and Child Health" event, planned for July or October, and if they wish to be involved.

1.3 Line to take
2. SPEAKING POINTS

EBOLA:

• Thank [redacted] for the leadership J&J has demonstrated under IMI with an in-kind contribution of almost €50 million in ongoing projects\(^1\), as well as €89.6 million within the framework of the recent 'Ebola+' IMI call.

• Express the continued strong commitment of the European Commission to support research on Ebola, including a special focus on the development of various vaccine candidates.

• Congratulate [redacted] and [redacted] about the success of the London School of Hygiene and Tropical Medicine and Johnson&Johnson in the first call of the IMI 'Ebola+' programme and wish them success with their participation in these 3 (LSHTM), resp 4 (J&J) IMI-funded Ebola projects, in particular in the clinical trials of the J&J vaccine candidate in Western Africa.

• Underline the importance of the J&J participation in the 'Ebola+' call. It will allow demonstrating that the company is promptly responding to the public health emergency resulting from the Ebola pandemic, and invite J&J to continue this strong involvement to the future calls of 'Ebola+', and more generally, IMI2.

• Point out that the Ebola crises in Western Africa has clearly demonstrated the role research and innovation plays in the detection, response and control of such crises, but also for our preparedness and development of effective prevention.

• Recall that we now start to see a decline in the incidence of new Ebola cases.

• Enquire about contingency plans in the best case scenario of a steady decline in new Ebola cases, which will be challenging for the completion of the planned clinical trials.

• Enquire opinion on post-Ebola era:
  
  - What are the plans to continue research and innovation of potential interventions against Ebola in the absence of an active outbreak?
  
  - What did we learn from the current outbreak that will help us in the future response to similar outbreaks from Ebola virus or other pathogens?
  
  - What should be the research orientation in the 'peace-time' interval between outbreaks, and how could funders support it in the absence of industry interest?

\(^1\) J&J is participating in 30 out of 47 ongoing IMI-funded projects, [http://www.imi.europa.eu/content/ongoing-projects](http://www.imi.europa.eu/content/ongoing-projects).
EDCTP:
- Invite [redacted] to continue supporting the EDCTP through direct involvement in the programme, and through advocating for the initiative to different stakeholders.
- Enquire about how EDCTP can be more attractive to co-investment from industry.

Maternal and Child Health:
- Acknowledge the J&J's currently ongoing but soon ending (2010-2015) initiative of 'Every Mother, Every Child', dedicated to improving the health of women and children in developing countries.
- Inform that DG RTD is planning to organise a conference in 2015 on 'Maternal and Child Health- the role of research and innovation' within the framework of the 'European Year of Development', either in July (as part of the thematic month on "Children and Youth") or in October (which is on "Food Security").
- Explain the idea to use this conference to discuss the contribution research and innovation have made towards the achievement of the Millennium Development Goals in reducing child mortality and improving maternal health and how we move forward.
- Indicate that we would like to launch a debate not only on what the international research community contributed to medical interventions but also on how their work was financially supported, in order words: what funding mechanisms were put in place, how did they work, and can we more efficiently support their work in the future?
- Indicate that you intend to get Vice-President Ms Mogherini and Commissioner Mr. Mimica involved in this conference as well.
- Enquire about [redacted] on this topic, and whether [redacted] would be interested to give input on the agenda or be member of the organising committee for this event, as well as to speak at the event.
3. DEFENSIVE POINTS

Should general strengthening of the health systems (health systems research) be a higher priority in Horizon 2020?

- One of the activity areas in the Health programme of Horizon 2020 is dedicated to public health, both in Europe and internationally. Capacity building and training activities are also addressed.

- This activity area covers a wide range of activities that aims to strengthen the health care systems in terms of functioning, structure and operational efficacy.

- But also in this area EDCTP plays an important role in training researchers, building research capacities, and supporting implementation research.

What is the European Commission currently doing on Maternal and Child Health and is there a need to continue the efforts?

- Within the context of reaching the Millennium Development Goals (MDGs) fighting poverty the European Union has provided more than €85 million in research projects as part of its 7th Framework Programme for research and technological development (FP7), to improve maternal and reproductive health and to help countries to create evidence for improving these services.

- As the Millennium Development Goal on "Improving Maternal Health" has not been achieved, women and children in developing countries still bear a disproportionate burden of disease whether infectious diseases or other. Because of this there is a need for more research to discover new and effective prevention and treatment methods, together with organisational models for the health services that should deliver them. H2020 should cater for those needs.

- In the current debates on the post-2015 development agenda continued support to maternal and child health has been called for. The Open Working Group (OWG) on the Sustainable Development Goals (SDGs)\(^2\) released a set of 17 recommended goals and 169 targets, in which Goal 3 claims "Ensure healthy lives and promote well-being for all at all ages" and consists of the following specific targets:
  - 3.1 By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births;
  - 3.2 By 2030, end preventable deaths of newborns and children under 5 years of age;
  - 3.7 By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health.

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\(^2\) The OWG was established following the 2012 United Nations Conference on Sustainable Development, commonly known as Rio+20.
4. ANNEXES

4.1 The EC's Research Response to Ebola
DG RTD has quickly mobilised €24.4 million from Horizon 2020 via an exceptional procedure to support urgent Ebola research. This procedure has never before been used by DG RTD, and the funding released is going towards five projects, with work having started on 1 November 2014 already. 75% of the funding has already been released to the projects.

1) EbolaVac – GlaxoSmithKline. Development of the most advanced vaccine candidate.


3) Ebola Tx – Prince Leopold Institute of Tropical Medicine (Belgium). Plasma from survivors of Ebola disease that contains antibodies. The LSHTM is a partner in this project,

4) IF-EBOla – Institute of Research for Development (France). Horse serum containing antibodies against Ebola.

5) EVIDENT – Bernhard-Nocht Institute for Tropical Medicine (Germany). Studies on transmissibility of the virus in various bodily fluids and mutations of the virus.

In addition, DG RTD is currently funding research addressing Ebola under FP7: on the development of new antiviral drugs, on linking up high-security laboratories, on the clinical management of patients particularly in Europe, and on solutions to ethical, administrative, regulatory and logistical bottlenecks that prevent a rapid research response. The on-going FP7 project PREPARE (Platform foR European Preparedness Against Re-emerging Epidemics), for instance, reacted to the Ebola epidemic by launching a survey of capacity and preparedness in PREPARE-affiliated hospitals in Europe, as well as an appraisal of evidence and knowledge gaps. The project has started to develop clinical study protocols and liaised with a network of high-containment facilities.

4.2 Ebola research funding under the IMI Ebola+ call
A second IMI2 call for proposals was launched in response to the Ebola crisis and related diseases in West Africa, as part of a new programme named “Ebola+” for Ebola and other filoviral haemorrhagic fevers. This Call for proposals launched on 6 November 2014 under the new Ebola+ programme has a total budget of €215 million which will go towards eight projects addressing development and manufacturing of vaccines, ensuring compliance with vaccine regimens, and the development of rapid diagnostic tests. €114 million comes from Horizon 2020, and the remaining €101 million from the pharmaceutical companies involved in the projects.

The projects include partners from around the world (mainly Europe, Africa, and North America). The topics are among the key priorities set out by the World Health Organization in the current Ebola crisis:

- Development of Ebola vaccines (3 projects)
  There are currently no licensed vaccines for Ebola. Three projects will advance the development of such vaccines by assessing the safety and efficacy of different vaccine candidates.
• EBOVAC1 – coordinated by the LSHTM (UK). Development (phase 1 and 3) of J&J vaccine candidate. **J&J involvement.**

• EBOVAC2 – coordinated by INSERM (FR). Development (phase 2) of the J&J vaccine candidate. **J&J involvement.**

• VSV-EBOVAC – coordinated by Sclavo Vaccines (IT). Analysis of the immune response to the rVSV vaccine candidate (Merck vaccine).

➤ **Scaling up vaccine manufacture (1 project)**
Ebola vaccines can be manufactured in facilities with a higher biosafety rating. This project will establish a platform capable of rapidly producing sufficient quantities of the vaccine, while adhering to stringent quality and safety requirements.

• EBOMAN – coordinated by Vibalogics (DE). **J&J involvement.**

➤ **Compliance with vaccine regimens (1 project)**
For a vaccine to have a real impact on an outbreak, high levels of vaccination coverage are essential. In addition, for lasting protection, two doses of the vaccine may be needed. The project will raise awareness of vaccination campaigns and aim to secure patient compliance for vaccines that require two doses.

• EBODAC – coordinated by the LSHTM (UK). **J&J involvement.**

➤ **Rapid diagnostic tests (3 projects)**
There is currently no fast, reliable test to determine if someone has Ebola or not. Three projects will pave the way for rapid diagnostic tests capable of delivering reliable results in as little as 15 minutes.

• Mofina
• Filodiag
• EbolaMoDRAD

The first projects have already started working as of 1 January 2015, and the hope is that they will deliver results that will contribute to tackling both the current and future outbreaks. It is expected that additional calls will be launched under the Ebola+ programme in 2015 and 2016 to address additional topics, e.g.: Multivalent filovirus vaccine development; Formulation for cold chain; Immunotherapy; Rapid diagnostic tests – long term; Antivirals development and repurposing; as well as discovery and early development of other products.

4.3 **The LSHTM and the EDCTP**
In addition to the FP7 projects, the researchers from the London School of Hygiene and Tropical Medicine have been actively involved in the FP6 EDCTP programme by providing expert advice or participating in EDCTP-funded activities. The current and previous chair of the EDCTP Partnership Board - which is the scientific advisory body of EDCTP - are researchers from the London School of Hygiene and Tropical Medicine (**LSHTM**).

In addition, there is a Member State Initiative (MSI) on capacity and network strengthening within the framework of malaria research in Tanzania coordinated by **LSHTM**. Partners in this project include the founding members of the Joint Malaria Programme (JMP) headed by **LSHTM**. Institutions involved in this MSI are the University of Copenhagen (UC), the London School of Hygiene and Tropical Medicine (LSHTM), Kilimanjaro Christian Medical Centre (KCMC) and the National Institute for Medical Research in Tanzania (NIMR). It is envisaged that the Radboud University Nijmegen Medical Centre (RUNMC) will be co-opted as a new member of JMP under the umbrella of this MSI.
4.4 Millennium Development Goal 4 "Reduce Child Mortality" and 5 "Improve Maternal Health"

The Millennium Development Goals (MDGs) were set at the 2000 Millennium Summit to accelerate global progress in development.

MDG 4 "Reduce Child Mortality": Progress is monitored through achievement of the following target (and their associated indicators):

- reduce by two thirds, between 1990 and 2015, the under-five mortality rate.

Despite population growth, substantial progress has been made towards achieving MDG 4. The number of under-five deaths worldwide has declined from 12.7 million in 1990 to 6.3 million in 2013. This translates into 17 000 fewer children dying every day in 2013 than in 1990. Despite determined global progress in reducing child deaths, an increasing proportion of child deaths are in sub-Saharan Africa and Southern Asia. Four out of every five deaths of children under age five occur in these regions.

About half of the world’s under-five deaths in 2013 still occurred in only five countries: India, Nigeria, Pakistan, Democratic Republic of the Congo, and China. India (21%) and Nigeria (13%) together account for more than a third of under-five deaths worldwide. Almost 75% of all child deaths are attributable to just six conditions: neonatal causes, pneumonia, diarrhoea, malaria, measles, and HIV/AIDS. Since 2000, measles vaccines have averted over 14 million deaths.

As the rate of under-five deaths overall declines, the proportion that occurs during the first month after birth is increasing. Children born into poverty are almost twice as likely to die before the age of five as those from wealthier families. Children of educated mothers—even mothers with only primary schooling—are more likely to survive than children of mothers with no education.

MDG 5 "Improve Maternal Health": Sexual and reproductive health is a prerequisite of all goals, particularly those related to gender and health. Progress is monitored through achievement of two targets (and their associated indicators) which are:

- Target 5.A. Reduce by 75%, between 1990 and 2015, the maternal mortality ratio;
- Target 5.B. Achieve, by 2015, universal access to reproductive health

Globally, an estimated 289 000 women died during pregnancy and childbirth in 2013, a decline of 45% from levels in 1990. Most of them died because they had no access to skilled routine and emergency care. Since 1990, some countries in Asia and Northern Africa have more than halved maternal mortality.

There has also been progress in sub-Saharan Africa. But here, unlike in the developed world where a woman's life time risk of dying during pregnancy and childbirth is 1 in 3700, the risk of maternal death is very high at 1 in 38. Increasing numbers of women are now seeking care during childbirth in health facilities and therefore it is important to ensure that quality of care provided is optimal.

Globally, over 10% of all women do not have access to or are not using an effective method of contraception. It is estimated that satisfying the unmet need for family planning alone could cut the number of maternal deaths by almost a third.

4.5 The Innovative Medicines Initiative

IMI is the world's largest public private partnership in health research. It has been created between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). EFPIA represents 33 national associations and 40 leading pharmaceutical companies.
Over the last seven years, €2 billion was invested to speed up the development of better and safer medicines for patients, in areas such as antimicrobial resistance, Alzheimer's and autism. Eleven calls for proposals were launched that resulted in close to 60 projects bringing together partners from different sectors (academia, SMEs, patient organisations, regulators and EFPIA companies). Industry funds its own research efforts (in-kind contributions) and EU funding pays for participation of the other partners. Achievements have already been seen in many phases of R&D:

- New screening methodologies both pre-clinically and clinically e.g., in diabetes and Alzheimer’s disease;
- More rapid identification of new therapeutic targets in areas of high unmet need such as autism and schizophrenia;
- Predictive toxicology and safety;
- Enhanced clinical trial design;
- Breakthrough in diabetes research – development of first human pancreatic beta cell line that survives in lab.

![Corporation contribution vs IMI funding](image)

4.6 London Declaration on Neglected Tropical Diseases


Website of the initiative: [http://unitingtocombatntds.org/resource/london-declaration](http://unitingtocombatntds.org/resource/london-declaration)
LONDON DECLARATION ON NEGLECTED TROPICAL DISEASES

For decades, partners including pharmaceutical companies, donors, endemic countries and non-government organisations have contributed technical knowledge, drugs, research, funding and other resources to treat and prevent Neglected Tropical Diseases (NTDs) among the world’s poorest populations. Great progress has been made, and we are committed to build on these efforts.

Inspired by the World Health Organization’s 2020 Roadmap on NTDs, we believe there is a tremendous opportunity to control or eliminate at least 10 of these devastating diseases by the end of the decade. But no one company, organization or government can do it alone. With the right commitment, coordination and collaboration, the public and private sectors will work together to enable the more than a billion people suffering from NTDs to lead healthier and more productive lives – helping the world’s poorest build self-sufficiency. As partners, with our varied skills and contributions, we commit to doing our part to:

- Sustain, expand and extend programmes that ensure the necessary supply of drugs and other interventions to help eradicate Guinea worm disease, and help eliminate by 2020 lymphatic filariasis, leprosy, sleeping sickness (human African trypanosomiasis) and blinding trachoma.
- Sustain, expand and extend drug access programmes to ensure the necessary supply of drugs and other interventions to help control by 2020 schistosomiasis, soil-transmitted helminthes, Chagas disease, visceral leishmaniasis and river blindness (onchocerciasis).
- Advance R&D through partnerships and provision of funding to find next-generation treatments and interventions for neglected diseases.
- Enhance collaboration and coordination on NTDs at national and international levels through public and private multilateral organisations to work more efficiently and effectively together.
- Enable adequate funding with endemic countries to implement NTD programmes necessary to achieve these goals, supported by strong and committed health systems at the national level.
- Provide technical support, tools and resources to support NTD-endemic countries to evaluate and monitor NTD programmes.
- Provide regular updates on the progress in reaching the 2020 goals and identify remaining gaps.

To achieve this ambitious 2020 vision, we call on all endemic countries and the international community to join us in the above commitments to provide the resources necessary across sectors to remove the primary risk factors for NTDs—poverty and exposure—by ensuring access to clean water and basic sanitation, improved living conditions, vector control, health education, and stronger health systems in endemic areas.

We believe that, working together, we can meet our goals by 2020 and chart a new course toward health and sustainability among the world’s poorest communities to a stronger, healthier future.
4.7 IMI- and FP7-funded projects with the J&J participation

J&J is strongly involved in European research cooperation and has shown leadership under the regular calls for proposals under IMI. J&J is involved in 13 FP7-and 30 IMI- funded projects, of which two as coordinator, namely the projects "Development of RApid Point-of-Care test Platforms for Infectious Diseases (RAPID-ID)" and "European Medical Information Framework (EMIF)").

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4.8 BACKGROUND INFO

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London School of Hygiene and Tropical Medicine

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