


<p><b>GA 101003666</b>  <b>Start date: 01/04/20</b>  <b>End Date: 31/03/22</b></p>	
<p><b>Project Title</b></p>	<p>OPENCORONA</p>
<p><b>WP number, deliverable number, and Title</b></p>	<p>WP8  D8.2  Project risk management plan</p>
<p><b>Responsible partner name and contact</b></p>	<p>Partner number: 1  Organisation: Karolinska Institutet  Name: Hanna Gador  Email: hanna.gador@ki.se</p>
<p><b>Nature</b>  R-Report  P-Prototype  D-Demonstrator  O=-Other</p>	<p>R, Document report</p>
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<p><b>Delivery Month Planned</b></p>	<p>M6 – 30 September 2020</p>
<p><b>Actual delivery date (dd/mm/yy)</b></p>	<p>11 November 2020</p>



# Description of deliverable

- **COMPLETED**

- We have created a Project Risk Management Plan together with a monitoring tool for the OPENCORONA consortium in order to monitor the risk management activities and associated communication between partners and the project management team regarding follow up of both already foreseen and new risks. They are both available for the consortium at our intra net file sharing tool. The risks will be regularly updated as changes arise, by both the Management team and the participants.

- **ANNEXES**

Risk Management Plan for the OPENCORONA project



# Risk Management Plan

<b>Project Acronym:</b>	OPENCORONA
<b>Grant Agreement No:</b>	101003666
<b>Project Duration:</b>	1 April 2020 – 31 March 2022
<b>Responsible Partner:</b>	Karolinska Institutet Name: Hanna Gador E-mail: hanna.gador@ki.se
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<b>Version 1</b>	M6

Document History			
Version	Date	Author	Description
1.0	October 2020	Hanna Gador	Established Plan v1.0

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## Executive summary

The performance of a project can be impacted by risks and opportunities that is presented at the start of the project as well as throughout the project's life. To identify, monitor and mitigate risks as well as opportunities through the project is therefor of importance.

The risk and management plan is established according to the OPENCORONA project Grant Agreement no 101003666 WP8 in order to provide a plan for the threats and opportunities that might impact the project performance.

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## Acronyms

OPENCORONA	Rapid therapy development through Open nCoronavirus Vaccine Platform
GA	Grant Agreement No 101003666
WP	Work Package according to Grant agreement Annex 1
PSM	Project Steering Committee
PC	Project Coordinator
PMO	Project Management Office, the coordinators management team

## Introduction

The aim of this plan is to encourage project participants to openly communicate risks within the consortium and to find a mitigation strategy to decrease negative impact of the project. The aim of the plan is to encourage all participants to report any risks so that they can be identified, categorized, monitored, and develop appropriate responses together with the WP leaders and PMO.

Annex 1 provides a detailed risk register including information on risk likelihood and impact.

## Risk management plan

[Risk assessment: risk identification, categorization and mitigation.](#)

The regular risk assessment will be led by the WP leader in communication and encouragement by PC and PMO. The PMO will collect and compile all input received from WP leaders. The risk assessment will be performed throughout the project and risks will be escalated to the PSC meetings for a broader discussion and assessment.

## Continuous risk monitoring

WP leaders will be encouraged by PC and the PMO to update the risk register. The participants has access through the internal tool OPENCORONA Box our monitoring document "OPENCORONA Critical Implementation risks and mitigation actions". The PMO will continue to discuss the risk monitoring as a recurring agenda item during their meetings as well as during the PSM:s.



The PMO will report, follow up and correspond mitigation strategies to the consortium at regular timepoints or as they arise.

## Overview of times and tasks for risk monitoring

Continuous risk monitoring	Request from	Request to	Timeline
Request each WP leader to update the risk register in view of logged risks and identify new risks	PMO	WP Leader	Prior to meetings, and/or as the issues arise
Finalize updated risk register	PMO	n.a.	As they arise
Reporting to PSC	n.a.	PMO, WP Leaders	At every PSC meeting
Report to EC	n.a.	PMO	At reporting periods, project meetings and as required
Discuss risk monitoring	PMO	n.a.	As recurring PMO discussion point.

## OPENCORONA overview of risks

### OPENCORONA Critical Implementation risks and mitigation actions

Risk number	Description of risk	Level of risk	WP Number	Proposed risk-mitigation measures	Updated risk level	Impact	Reason for update	Updated by and when
1	Vaccine candidate not immunogenic	Low	WP1, WP2, WP3, WP4, WP5, WP6, WP7, WP8	Several vaccine candidates generated and tested, delivery optimisation				
2	Vaccine candidate causes cytokine storm	Medium	WP2, WP3, WP4, WP5, WP6, WP7, WP8	Several vaccine candidates generated and tested				
3	The vaccine candidate does not protect the challenge mice	Low	WP3, WP4, WP5, WP6, WP7, WP8	Several parallel vaccine concept will be developed by WP1				
4	In vivo EP not tolerable	Low	WP4, WP5, WP6, WP7, WP8	Cliniporator has been used extensively in clinical practice, extensive experience,				



				adjust pulse patterns
5	Plasmid can not grow	Low	WP5, WP6, WP7, WP8	Several vaccine candidates generated and tested
6	Plasmid toxic	Low	WP6, WP7, WP8	Several vaccine candidates generated and tested
7	Study not approved by ethics committee or MPA/EMA	Low	WP7	Early contacts and Scientific advice with MPA/EMA
8	Clinical trial fails to show safety	Low	WP7	All vaccine candidates are analysed for toxicological effects in vitro and in vivo in animal models. Toxicological studies are performed according to GLP and all data is analyzed by the Swedish MPA/EMA before approval of the clinical trial.
9	Clinical trial fails to show immunogenicity	Medium	WP7	The selection of the vaccine candidate is done in the best animal models. The immunogenicity is thoroughly evaluated in larger animals such as rabbits. Only highly immunogenic candidates are evaluated further.

