

HollandPTC- Varian Grant Rules

V1.1

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1. Introduction

The HollandPTC-Varian Grant Rules contain the terms and conditions applicable to the awarded grants by HollandPTC-Varian, as a result of the HollandPTC-Varian consortium-confined calls. The rules are based on the conditions stated in the Research Agreement between Varian and HollandPTC (dated 27th of November, 2014) and the Research Collaboration Agreement between HollandPTC and the academic institutes (dated 1st of January 2018), as further determined in a project agreement.

This document depicts a summary of these conditions containing practical information for the researchers/applicants. The Grant Rules apply to all applicants of the HollandPTC-Varian consortium-confined calls. Application- and selection procedure regarding the calls are not part of these rules, those can be found in the *Call Protocol*, as published on the HollandPTC website.

2. General principles

2.1. Intellectual property

For the HollandPTC-Varian consortium-confined calls, the IP conditions stated in the research agreement between HollandPTC and Varian apply as further determined in a project agreement. They are not subject to negotiations. Please pay attention; any IP resulting from a project accepted for the HollandPTC-Varian consortium-confined call will be jointly owned. A summary of the IP conditions can be found in appendix 1.

The researcher shall provide prompt written notice of any and all documentary deliverables and inventions to Varian (with cc to HollandPTC Research Office and Erasmus MC, IP portfolio manager) send to the following email addresses:

- Michel Closset, Varian michel.closset@varian.com
- IP portfolio manager IPmanager@hollandptc.nl
- HollandPTC Research Office researchoffice@hollandptc.nl

2.2. Publications

Projects resulting from the HollandPTC-Varian calls are subject to the *HollandPTC publication rules and guidelines* which are mandatory and can be found in appendix 2. Besides the HollandPTC-specific publication rules, the following publication rules apply:

It is mandatory to send an early notification of any planned publication or presentation ('whether written or oral and whether public or private') to HollandPTC and Varian at different time points. This means the following:

1. Before the submission of any planned publication or presentation first an early notification should be send to the *Research Office*. Any objection to the planned publication by the Programme Board will be send within 30 calendar days. If no objection is made within this time, the planned publication is permitted.
2. If no objections are made at the previous step, a notification to Varian should be send as follows:
 - Before the submission of any proposed written publication a copy of this written publication should be send to Varian (cc to Research Office). Varian can evaluate this

during a period of *14 working days* (with possible extension to determine whether Varian wishes to file a patent application).

- Before the submission of any presentation a summary of any proposed oral disclosure or poster abstract should be sent to Varian (cc to Research Office). Varian can evaluate this during a period of *7 working days* (with possible extension to determine whether Varian wishes to file a patent application).

- Michel Closset, Varian michel.closset@varian.com
- HollandPTC Research Office researchoffice@hollandptc.nl

Please keep in mind that the *HollandPTC publication rules and guidelines* indicate that all publications should refer to HollandPTC, and that at least one of the authors should use the affiliation HollandPTC (if contracted by HollandPTC) or refer to the HollandPTC consortium, using the following affiliation:

HollandPTC:

'HollandPTC, Delft, the Netherlands'

HollandPTC consortium:

'HollandPTC consortium – Erasmus Medical Center, Rotterdam, Holland Proton Therapy Centre, Delft, Leiden University Medical Center (LUMC), Leiden and Delft University of Technology, Delft, The Netherlands'

2.3. HollandPTC PhD programme

In the next years HollandPTC will create a HollandPTC PhD programme. As part of this programme, PhD candidates are stimulated to share their research with each other and to learn about proton irradiation related research and research within HollandPTC. The PhD students involved in the projects resulting from the HollandPTC-Varian calls will be strongly encouraged to join the events.

2.4. PPS funding

HollandPTC and the academic parties submit a proposal for PPS funding to the Netherlands Enterprise Agency (*Rijksdienst voor Ondernemend Nederland*). Therefore, it is not possible to apply individually for PPS funding for the projects resulting from the HollandPTC-Varian calls.

3. The Project

3.1. General

3.1.1. Responsibilities

- The main applicant is responsible for the proper management and administration of the grant resources.
- The main applicant will ensure that the project complies with the grant conditions when carrying out the project and that the grant is spent effectively.
- The main applicant will ensure that the employee recruited for the granted research position holds the required qualifications.

3.1.2. Execution in accordance with research plan

- The main applicant shall conduct the research project according to the research plan for which the grant was awarded.

3.2. Commencement of the project

3.2.1. Start form

A project can only commence once the 'Start form' has been signed by all parties and returned to the Research Office of HollandPTC. The start form will be sent to the main applicant of the project. Before the official start of the project, HollandPTC and the academic institutes will ensure that a project agreement has been established and signed by all parties. Make sure you will save a copy of the agreement for your own administration.

The start date of a project can be set to April 1st or October 1st.

3.2.2. Payment (first tranche)

Payments will be made in six-month tranches. The start date of the project determines the payment of the first tranche of pre-funding. Please note, all payments will be made as a pre-payment. The exact amounts are stated in the individual start forms. The intention is to transfer the first-tranche of pre-funding to your institute around the beginning of May or the beginning of November, depending on the start date. HollandPTC will only release the funding upon receipt of the funding from Varian. In no case HollandPTC will pre-finance the costs. HollandPTC will transfer the money upon receipt of Varian within 10 working days.

3.2.3. Recruiting staff for the granted research position

When recruiting staff for the granted research position, you will find the text regarding HollandPTC, which has to be added to your vacancy notice, in appendix 3. Please also add the HollandPTC logo.

3.3. Progress of the project

3.3.1. Informing the Research Office

The Research Office of HollandPTC should be informed with the following information, no later than two weeks upon decision:

- Name and contact details of the person who fulfills the granted research position
- Formal approved protocols (including confirmation of approval) regarding your research (CCMO/CME/MREC, DEC/CCD, etc.).

In case your research (partly) takes place at HollandPTC (either clinical studies or studies using HollandPTC R&D facilities) please take notice of the procedures published on the HollandPTC website. This includes information about i.e. how to apply for beam-time and get your experiments scheduled.

3.3.2. Biannual progress reports and budget update

Each year on the 15th of March and the 15th of September at latest, the main applicant shall provide HollandPTC with a comprehensive written report of the progress of the research project (according to the instruction page in appendix 4 and the template in appendix 5) together with an update of the budget. The progress report and budget update templates can be downloaded from the HollandPTC website as a WORD and EXCEL file. The progress report is meant to be an overview, not a report of daily changes. It serves as documentation that you are making reasonable progress on your project.

The report and budget update should be send to the research office stating: 'progress report + *reporting period* + your *HollandPTC projectcode*'. The report and budget update have to be received before **12h CET on March 15 and September 15 of each year.**

Please take notice; the release of your funding of the next tranche will only take place upon receipt of the progress reports.

For general questions about reporting and the budget please contact the research office:

Research Office HollandPTC researchoffice@hollandptc.nl +31 (0)88 501 11 86

If you have any specific questions for Varian about how to prepare your report, please contact either:

Michel Closset michel.closset@varian.com

3.3.3. Payment

Payments will be made as a pre-payment which take place according to the payment schedule (as stated in the start form) upon receipt of progress reports and budget updates. If progress reports are accepted, it is the intention to transfer the next tranche of pre-funding to your institute around the beginning of May and beginning of November. HollandPTC will only release the funding upon receipt of the funding from Varian. In no case HollandPTC will pre-finance the costs. This means that in case the reports are not received on time, payments will be delayed by half a year. HollandPTC will transfer the money upon receipt of Varian within 10 working days.

3.4. End of the project

3.4.1. Final report and budget update

Within 60 days after the expiration or termination of the project, the main applicant shall provide the HollandPTC Research Office with an update of the budget, according to the template which can be found on the HollandPTC website.

Within 120 days after the expiration or termination of the project, the main applicant shall provide HollandPTC with a comprehensive final report describing all results of the project and all inventions, documentary deliverables and intellectual property created in the course of the research project in reasonable detail.

3.4.2. Accountability regarding PPS funding

For reporting purposes of RVO (regarding the PPS funding) it is important to keep (time) records, in accordance with the PPS rules “*Kaderbesluit (nationale) EZ-subsidies*”. An audit report is required at the end of the project for each recipient.

Furthermore, within 60 days after the end of your project, each academic party shall send TU Delft (as project coordinator for the PPS funding) and the HollandPTC Research Office a final accounting of all expenses incurred in connection with the Research Plan and all funds received from HollandPTC. The final accounting shall meet the terms and conditions of the PPS funding and the “*Kaderbesluit (nationale) EZ-subsidies*”. Within 60 days from HollandPTC’s receipt of such final accounting, the Academic Parties shall settle all payments and overpayments.

Please send the accountability to the following email addresses:

- Micheline Lausberg, TU Delft M.Lausberg@tudelft.nl
- Karin van der Graaf, TU Delft K.vanderGraaf@tudelft.nl
- Emelie van Bentum, TU Delft E.A.M.vanBentum@tudelft.nl
- HollandPTC Research Office researchoffice@hollandptc.nl

3.4.3. Payment (last tranche)

The last tranche of funding will be released upon approval of the final report by Varian and after a final calculation according to the expenses of the project has been made.

4. Contact details

For any questions please contact the HollandPTC Research Office:

Research Office HollandPTC researchoffice@hollandptc.nl +31 (0)88 501 11 86

Appendix 1: Summary IP conditions

Summary HollandPTC-Varian agreement

- Varian has contributed an in-cash financial support for research projects to be conducted (primarily) at the facility of HollandPTC. Erasmus Universitair Medisch Centrum Rotterdam (“Erasmus MC”), Academisch Ziekenhuis Leiden (“LUMC”) en de Technische Universiteit Delft (“TU Delft”) (the “Academic Parties, each an Academic Party”) will conduct such research projects.
- HollandPTC and Varian agreed that all foreground IP (i.e. intellectual property rights with respect to any Documentary Deliverables and Inventions (*defined below*)) shall be jointly owned by Varian and the Academic Party conducting the research, save one of the parties obtains sole ownership of foreground IP subject to payment of a price in line with the market. Each party shall be entitled to obtain sole ownership of Foreground IP based on fair and reasonable terms for the other party’s undivided share in such Foreground IP which is in line with the market. Following a written notice that a party wants to acquire sole ownership of any Foreground IP, the parties shall in good faith jointly determine a price. If parties are not able to determine a price the parties shall in good faith jointly appoint an independent expert who shall be commissioned to determine the price.
- At all times each Academic Party shall have the irrevocable, royalty-free right to use the Documentary Deliverables and Inventions for purposes of internal research and clinical use. When foreground IP is jointly owned, both Varian and the relevant Academic party have the right, and have been granted with a non-exclusive, non-assignable royalty free licence to use the Documentary Deliverables and Inventions for any purpose, including, but not limited to, commercial exploitation.
- If Foreground IP is jointly owned, the relevant parties shall mutually agree whether or not to file an application for and/or prosecute any or all foreground IP and may jointly file an application for and/or prosecute such foreground IP. In the event either party determines that it does not want to prosecute certain foreground IP, then such other party shall have the right to file an application for and/or prosecute such foreground IP. The joint applications for foreground IP shall be filed in the name of Varian and the relevant Academic Party jointly. In case a party has sole ownership of foreground IP, such foreground IP shall be filed in the name of such Party. The party to file an application for foreground IP shall bear the expense of preparing, filing and prosecuting such application, and maintenance for any foreground IP that may issue therefrom. The parties shall reasonable cooperate with each other in these activities.
- Promptly upon the making, arising or other creation of any Invention and/or in a tangible medium of any Documentary Deliverable, the relevant Academic Party shall provide written notice to Varian of such Invention or Documentary Deliverable. If Varian is the sole owner of an Invention, Varian shall determine the type of protection, in any, to be sought with respect to such Invention and the timing for seeking such protection.
- Each Academic Party shall be free to disclose publicly Inventions through journals, lectures or otherwise, provided the following. Such Academic Party shall give HollandPTC and Varian prior written notice of an intended disclosure to any third party, whether written or oral and whether public or private, with a copy of each proposed written publication or a summary of any proposed

oral disclosure within a period prior to publication or disclosure that is sufficient for Varian for compliance with this provision. During a period of 14 working days or 7 working days for a poster abstract following HollandPTC's and Varian's receipt of such notice, HollandPTC and Varian may:

- (i) advise such Academic Party that it has no objection to the intended disclosure, in which case such Academic Party may proceed with the intended disclosure;
 - (ii) identify confidential information in the intended disclosure, which such Academic Party shall remove, and upon confirmation that such confidential information has been removed from the intended disclosure, such Academic Party may proceed with the intended disclosure;
 - (iii) notify such Academic Party that it requires an extension of the review period with a further 6 working days to determine whether it wishes to file a patent application, in which case such Academic Party shall not proceed with the intended disclosure until the end of the extended review period; and
 - (iv) notify such Academic Party that it wishes to file a patent application, in which case such Academic Party shall not proceed with the intended disclosure until such patent application has been filed, but in no event later than 90 days after the end of the (extended) review period.
- In no event Varian and/or HollandPTC has editorial control over the intended disclosure.
 - All publications (including, but not limited to, scientific papers and presentations) related to a research project shall make reference to HollandPTC in accordance with the publication rules and guidelines of HollandPTC as published on its website and provided upon request at the research office of HollandPTC.
 - *"Documentary Deliverables"* means all aspects of any copyrightable computer code, including object code and source code, created or in any way developed in the course of a research project or related to an Invention.
 - *"Invention"* means any invention, development, discovery, technology, know-how, process, technique, protocol, data, formula and any other creation based on or arising from the research project or from use of equipment, information or other resources provided by HollandPTC to any Academic Party other than the proton system sold by Varian to HollandPTC and conceived or reduced to practice during the term of the agreement and under the conditions of this Agreement by any employee, consultant or other agent of HollandPTC or of an Academic Party or of HollandPTC and an Academic Party, or Academic Parties jointly.

Appendix 2: Publication rules and guidelines

When do these rules and guidelines apply?

The HollandPTC publication rules and guidelines are mandatory for all projects which include (I) a *substantial* in-kind contribution of HollandPTC (e.g. HollandPTC provides expertise and/or research facilities, such as labs, the R&D bunker, gantries, clinical imaging modalities and the prospective research database) and/or (II) *any* industry funding allocated to HollandPTC. A full list of the research facilities can be found on the HollandPTC website.

Regarding all other projects which are (partly) performed at HollandPTC but do not match the criteria above, the rules below can be considered as guidelines.

What are the rules and guidelines?

For all scientific publications (including, but not limited to, scientific papers and presentations) attention should be given to the contribution of all authors, authorship order and potential conflicts of interest. HollandPTC follows the research codes of Erasmus MC and LUMC ('Erasmus MC Research Codes' and the 'LUMC Researchcode'). Furthermore, HollandPTC follows the ethical standard of conduct and reporting of research described by the 'Netherlands Code of Conduct for Research Integrity' and the general consensus of ethical standard in biomedical journals given by the International Committee of Medical Journal Editors (ICMJE) in their 'Recommendation for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals'.

Apart from these codes and standards, the following HollandPTC-specific rules apply:

1. All publications (including, but not limited to, scientific papers and presentations) should refer to HollandPTC.
 - a. Regarding scientific publications: this can either be done in the Method section or the Acknowledgements (see #2).
 - b. Regarding presentations: at least the HollandPTC logo should be used (see #3).
2. For all scientific publications at least one of the authors should use the affiliation HollandPTC (if contracted by HollandPTC) or refer to the HollandPTC consortium (see below). Thus:
 - a. A co-author that is contracted by HollandPTC should refer to their HollandPTC affiliation.
 - b. In the case none of co-authors holds an employment at HollandPTC, the HollandPTC *consortium* affiliation should be used.
3. For presentations (oral and poster) the HollandPTC PowerPoint templates (when research *largely* takes place at HollandPTC) is preferred, but the use of correct name and logo is mandatory.
4. The Research Office should receive a notification at least thirty days before the submission of a planned publication (or presentation abstract). The Programme Board has 30 days to evaluate the planned publication. If no objection is made within this time, the planned publication is permitted.

How do I refer to HollandPTC or the HollandPTC *consortium*?

Any referral to HollandPTC, either by author affiliation of an employee or otherwise, should be:
'HollandPTC, Delft, the Netherlands'.

Any referral to the HollandPTC *consortium* should be:
'HollandPTC consortium – Erasmus Medical Center, Rotterdam, Holland Proton Therapy Centre, Delft, Leiden University Medical Center (LUMC), Leiden and Delft University of Technology, Delft, The Netherlands'

Appendix 3: Vacancy text regarding HollandPTC - research positions

Please mention the following text together with the HollandPTC logo:

HollandPTC's mission is to provide patients with the best proton therapy presently available, in a safe and welcoming environment, where they are treated with care and diligence. You will be part of the HollandPTC R&D program. Our mission is to prove the added value of proton therapy, which we do in cooperation with the national and international radiotherapy and oncology community.



Optional additional information about HollandPTC:

The Holland Proton Therapy Centre (HollandPTC), founded by Erasmus Medical Centre, Leiden University Medical Centre and TU Delft, is an active partnership between these organizations in which they collaborate in the fields of healthcare, education, and groundbreaking research. The Centre has also established partnerships with other national and international proton centers.

HollandPTC is an independent outpatient clinic and research centre, located in Delft. The centre has two proton gantries with in-room CT imaging, a treatment room for the irradiation of eye tumors, and a bunker with a proton bundle for research. In addition, the centre has modern imaging equipment, including a dual-energy CT, a 3T MRI, and a PET/CT.

Appendix 4: Progress Report – Instruction Page

A Progress Report serves as documentation that you are making reasonable progress on your project. It is added to your file and auditable.

If you have any questions about how to prepare your report, please contact either:

Timo Berkus, PhD	timo.berkus@varian.com	+41 78 9098007
Scott Johnson, PhD	scott.johnson@varian.com	+1 773-490-4721
Anthony Lujan, PhD	anthony.lujan@varian.com	+1 312-391-1976

Instructions

Please be brief but as complete as possible.

Completed reports should comply with the following:

- Font size: 11 point
 - Font: Times New Roman
 - Margins: 1 inch on all sides
1. **Effective Dates of your Project.** Please enter the project's Start Date and End Date. This is the start date as stated on your Start Form.
 2. **Reporting Period.** Please enter the date range of the reporting period. The Start Date typically is the date of your previous progress report. The End Date is the date of this report.
 3. **Management Summary.** Please provide a high level overview on the current status of the project.
 4. **Project Overview.** Please insert your Project Overview (or Hypothesis Statement). You may copy and paste it from your proposal. Also, you have the option to update your Project Overview based upon lessons learned during the course of your research.
 5. **Specific Aims.** Please insert Specific Aims. You may copy and paste them from your proposal. If a particular aim has been completed, please mark it as Completed.
 6. **What has been done?** Please describe your progress in the current reporting period. Below, you will indicate which Milestones have been met and which have not. If Milestones have not been met as intended, please describe why and how your Research Plan will be adapted as a result. Please describe and explain any deviations from your proposed Research Plan or timeline.
 7. **Lessons Learned.** Please describe what you have learned in the current reporting period and why it is important.
 8. **Milestones.** Copy and paste from your Milestones from your proposal and indicate Met, Partially Met, or Not Met.
 9. **Deliverables.** Provide a list of Deliverables for the current reporting period.

10. **Manuscripts, Abstracts, Presentations.** Please list project-related publications, abstracts, presentations and invention disclosures for the current reporting period. Do not list items previously reported. Please note, items in this section should have been submitted to your Varian Technical Representative, as described in your Research Agreement. If they were not submitted, please submit them now.
11. **Invention Disclosures.** Please describe any inventions for the current reporting period. Do not list inventions previously disclosed. If the inventions disclosures were not submitted previously, please submit them now.
12. **Upcoming Project Plan.** Please summarize the research plan to complete the specific aims remaining in your proposed project from now until the end of the project.

Appendix 5: Template progress report

WORD file can be downloaded from the HollandPTC website

HollandPTC-Varian consortium-confined call 2018/2019/2020/2021*	
Sub-project nr.	<i>Filled out by HollandPTC</i>
HollandPTC projectcode	

Date:	
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Title:	
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Institution:				
Principal Investigator(s):				
Co-Investigators(s):				
Contact Info	Phone:		Email:	

1. **Effective Dates of the Project:**

Start Date:

End Date:

2. **Reporting Period:**

Start Date:

End Date:

3. **Management Summary:**

4. **Project Overview:**

5. **Specific Aims:**

Specific Aim 1:

Specific Aim 2:

And so on.

6. **What has been Done:**

7. **Lessons Learned:**

8. **Milestones:**

9. **Deliverables:**

10. **Manuscripts, Abstracts, Presentations:**

11. **Invention Disclosures:**

12. **Upcoming Project Plan:**