Date Thesis Submitted: 08/03/2024 Actual Word Length: 47897

The University of Birmingham Registry - Academic Services

DOCTORAL REPORT FORM PART ONE: INDEPENDENT REPORT ON THESIS

(A JOINT REPORT IS NOT ACCEPTABLE)

Independent Report normally 500 words which should address the following.

- a) Was the nature and purpose of the research made clear and was this substantially achieved?
- b) To what extent does the thesis demonstrate that the candidate has an adequate understanding of the subject and knowledge of the literature? Is there coverage of recent and relevant literature in the field of study which shows critical appraisal and an original synthesis?
- c) Has the candidate chosen the appropriate methodology for the study? Is the methodology then used effectively? Are the findings interpreted in a valid way?
- d) What evidence is there of independent critical and analytical skills, and the ability to evaluate evidence?
- e) Is there an understanding of the theoretical field associated with the study? Is the linkage and balance between practical investigation and theory satisfactory?
- f) Are the arguments put forward in an appropriate and coherent form?
- g) To what extent does the thesis show evidence of originality and make a contribution to knowledge? Does it contain matter suitable for publication in whole or in part in a learned journal or the equivalent?
- h) What is your view of the overall quality of the research described in the thesis?
- i) Is the synopsis an adequate summary of the work presented?
- j) Is the thesis clearly written and presented? Is the style and structure of the thesis satisfactory?
 - a) The purpose of the research is to facilitate the implementation of novel advanced statistical methodologies in early phase cancer trials. The barriers to this have been adequately identified and solutions to tackle it are proposed in the thesis. One of the barriers stated is the lack of ready-to-use software. At the same time, the candidate did not provide the open-source software for all chapters of the thesis. One of the chapters contains the R Shiny App but not the open-source code to it.
 - b) A number of chapters contain a critical review of the literature in the corresponding field, and for some of the chapters the review is comprehensive. At the same time, the criteria for selecting the paper for review are unclear, e.g. why some have been missed. Importantly, for Chapter 2, major references to the recent implementation of the same methodologies (POCRM) are missing and the most recent ones date to years ago. For Chapter 3, the references to use control arm data in the dose-escalation model are also missing and are overlooked in the implementation which leads to incorrect/incomplete conclusions on the proposed methodology.
 - c) The chosen methodology is mostly appropriate and the proposed solution do facilitate the implementation of novel methodologies. At the same time, the interpretation of the implications of these solution is often vague. For example, for the dose/efficacy transition methodologies (Chapters 4 and 5) do not explicitly articulate the inter-link between the decision-trees provided/rules for the decision-making and the operating characteristics of the design, which is a major omission.
 - d) Previously proposed methodologies are evaluated and assessed and the simulation studies present a mostly comprehensive evaluation of statistical methods. However, as per above, the implications are not always articulated. Moreover, there are missing opportunities, for example for the TITE-CRM dose-transition pathways, the choice of the weight function is not discussed while the proposed tool can be a major addition to evaluation of this particular feature of the TITE designs.

- e) The overview of existing methodology is provided for some chapters (Chapter 2-3) but not for others (Chapter 5). The thesis focuses primarily on the practical aspects that, given the subject of the degree, is acceptable.
- f) The arguments provided in earlier chapters (Chapters 2-3) are appropriate and coherent but they are not in Chapters 4-5. As per above, the implications of change in the decision-making criteria are not comprehensively explored.
- g) Chapters 4 and 5 contain substantial contribution to knowledge and could be suitable for publication in a scientific journal. For Chapters 2 and 3, due to the gaps in the literature review, these sections in many aspects repetitive to existing evidence.
- h) Overall, the research described is of a good quality with the major contributions being Chapters 4 and 5.
- i) The synopsis is an adequate summary of the work presented
- j) In earlier chapters, the writing is clear. In the latter chapters, however, the candidate uses a non-scientific language/style, there are many ambiguous terms, and a number of repetitions, which makes the analyses hard to read and comprehend.

Please return this part BEFORE the Oral, (keeping a copy for yourself) to Research Student Administration Team via e-mail to pgrstudentrecords@contacts.bham.ac.uk.

Date Of Oral (please insert)	21 June 2024
An oral examination is compulsory for a doctoral thesis	

Examiner	Name (Block Capitals)	Signature (if sending by e-mail insert "by e-mail"	Date
External	PAVEL MOZGUNOV	By e-mail	18 th June 2024

External

Date Thesis Submitted: 08/03/2024 Actual Word Length: 47897

DOCTORAL REPORT FORM PART TWO: JOINT REPORT ON THE ORAL EXAMINATION

A joint report (approximately 200 words), should be completed immediately after the oral examination and returned, with Parts 3 and 4, to Research Student Administration via pgrstudentrecords@contacts.bham.ac.uk.

Examiner	Name (Block Capitals)	Signature (if sending by e-mail	Date
An oral exa	mination is compulsory for a doct	oral thesis	
Date of Ora	l (please insert)		

insert "by e-mail"

Candidate's Name: A Patel Permitted Word Length: 50000 Date Thesis Submitted: 08/03/2024 Actual Word Length: 47897

DOCTORAL REPORT FORM PART THREE: FINAL RECOMMENDATION

- For definitions of minor and major corrections and revise and resubmit and their time limits, please refer to the Examiners Guidance Notes.
- Where a recommendation is minor or major corrections or revisions to the thesis, examiners must complete Part Four of the report.
- Where examiners agree, a joint Part Three report should be completed.
- Where examiners are unable to agree on a final recommendation, please refer to the Examiners
 Guidance notes. In this situation each examiner should complete a separate final recommendation
 form.

The whole examination process should be completed by 20 June 2024.

I/We	recommend: Tick One Op	ion
1.	That the degree for which the thesis was submitted be awarded	
2.	That the degree for which the thesis was submitted was submitted be awarded subject to minor corrections being carried out to the satisfaction of insert name of external examiner nominated to check the corrected thesis	
	Complete a list of corrections on Part 4.	
	The normal timeframe for completion of minor corrections is one month. Please state here if the examiners wish to give the candidate a longer period. Click here to enter text.	
	An electronic copy of the corrected thesis will be emailed to the external examiner for checking.	
	If you prefer to check a paper bound copy please tick here \Box	
3.	That the degree for which the thesis was submitted be awarded subject to major corrections being carried out to the satisfaction of both examiners.	
	Complete a list of corrections on Part 4.	
	The normal timeframe for completion of major corrections is six months. Please state here if the examiners wish to give the candidate a longer period. Click here to enter text.	
	An electronic copy of the corrected thesis will be emailed to both examiners.	
	If you prefer to check a paper bound copy please tick here \Box	
4.	That the thesis be revised and resubmitted for the degree for which it was submitted.	
	Complete a list of corrections on Part 4.	
	A further oral will be held following resubmission.	
	The normal timeframe for revision and resubmission is one year. Please state here if the examiners wish to give the candidate a longer period. Click here to enter text.	

5.	That th	e degree should not be awarded, but:		
	(Please	tick one of the following options)		
	a) Aw	ard an appropriate Masters degree.		
	(The ca	ndidate shall have the right of appeal.)		
	Enter p	rogramme title of Masters degree here: Cli	ck here to enter text.	
	b) Aw	ard an appropriate Masters degree (MPhil,	MA/MSc by Research, MRes (only app	olicable
	where 6	60 credits of taught modules have been co	mpleted), subject to Minor/Major*	
	correct	ions (*please delete as appropriate).		
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	Comple	ete a list of corrections on Part 4 of the repo	ort form.	
		rmal timeframe for completion of minor co		
	correct	ions six months. Please state here if the ex	caminers wish to give the candidate a l	onger
	period.	Click here to enter text.		
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	examin	ers for major corrections.		
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	comple	ted).		
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6.	inat th	e thesis be rejected, without opportunity f	or resubmission and a degree not awa	raea.
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Exte	rnal 1			
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Student ID: 2227725

Examiner	Name (Block Capitals)	Signature	Date
External 1			
External 2			

Date

Candidate's Name: A Patel Permitted Word Length: 50000

Examiner

External 1

External 2

Name (Block Capitals)

DOCTORAL REPORT FORM PART FOUR: LIST OF CORRECTIONS/REVISIONS

This part must be completed in all cases where the recommendation is minor or major corrections or revise and resubmit the thesis.

To remove any ambiguity examiners should be explicit in the guidance given with regard to corrections.

Corrections have been noted on the body of the thesis	YES	NO
If yes, has the thesis been returned to candidate	YES	NO

Completed Parts 2, 3 and 4 should be returned together to Research Student Administration Team via email to pgrstudentrecords@contacts.bham.ac.uk.

Signature

Candidate's Name: A Patel	Student ID: 2227725	Date Thesis Submitted: 08/03/2024
School/Department: Inst of Cancer / Genomic Sci		
Permitted Word Length: 50000		Actual Word Length: 47897

PART FIVE: EXTERNAL EXAMINERS' COMMENT ON ACADEMIC STANDARDS AND PROCEDURES

External examiners **are invited** to complete this form on the quality and standards of research degrees and administrative arrangements for the examination of research degrees at the University of Birmingham.

d below. If necessary, please continue on a separate sheet, which should be signed and dated.
our opinion:
Are the descriptor levels for research degree programmes (Regulation 6.1.3 https://intranet.birmingham.ac.uk/as/registry/legislation/regulations.aspx) set out on Page 2 of the Examiners Guidance notes of the appropriate standard and do they provide clear and sufficient guidance?
Yes/No/Not applicable
Comments:
Are the arrangements for Research Degree Programmes with Taught Elements clear and comprehensive (Regulation 6.1.4 available at:
https://intranet.birmingham.ac.uk/as/registry/legislation/regulations.aspx
Yes/No/Not applicable
Comments:
Are the requirements for the degree (Regulation 7.4.1 https://intranet.birmingham.ac.uk/as/registry/legislation/regulations.aspx) available on page 3 of Examiners Guidance notes of the appropriate standard?
Yes/No/Not applicable
Comments:
And the consequent requirements (Denvilation 7.4 quality labels at
Are the assessment requirements (Regulation 7.4. available at: https://intranet.birmingham.ac.uk/as/registry/legislation/regulations.aspx) appropriate and satisfactory?
Yes/No/Not applicable

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	recommendations available to examiners of the Examiners Guidance notes).	appropriate and satisfactory for each a	ward? (See		
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	o/Not applicable				
Comm	ents:				
Were th	e arrangements and procedures for all sta	ges of the examination satisfactory?			
	o/Not applicable				
Comm	ents:				
Were vo	ou satisfied that you understood your role	in the oral examination and that you w	ere able to		
	that role?	the Grane examination and that you h			
periorii	that role:				
Voc/Na	o/Not applicable				
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Commi	ents.				
	information provided to you offer you cle	ar guidance on your role and on the			
recomm	endations you could make?				
Yes/No	o/Not applicable				
Comm	ents:				
Do you	have any further comments on the quality	and standard of the University's resea	rch awards,		
process	ses or any other issues of wider concern about this candidate's research thesis or supervision				
which yo	ou would like to raise?				
Yes/No	o/Not applicable				
Comments:					
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	Name (Block Capitals)	Signature	Date		
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