

CRN East Midlands Quarterly Board Update

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Trust Board paper H

Purpose of report:

This paper is for:	Description	Select (X)
Decision	To formally receive a report and approve its recommendations OR a particular course of action	
Discussion	To discuss, in depth, a report noting its implications without formally approving a recommendation or action	
Assurance	To assure the Board that systems and processes are in place, or to advise a gap along with treatment plan	X
Noting	For noting without the need for discussion	

Previous consideration:

Meeting	Date	Please clarify the purpose of the paper to that meeting using the categories above
CMG Board (specify which CMG)		
Executive Board		
Trust Board Committee		
Trust Board		

This report was reviewed by CRN East Midlands Executive Group on 9 December 2020.

Executive Summary

Context

University Hospitals of Leicester (UHL) NHS Trust is the Host Organisation for the National Institute of Health Research (NIHR) Clinical Research Network East Midlands (CRN). UHL is contracted by the Department of Health and Social Care to take overall responsibility for the monitoring of governance and performance of the Network.

For the information of the Board, we have prepared this quarterly update on the recent progress and current priorities of CRN East Midlands. Appended to this report is a summary of COVID-19 research studies in the East Midlands, a table displaying the new CRN Performance Standards for 2020-21 and our current risks & issues register.

Questions

1. Since our October report, what have been the key areas of progress for CRN East Midlands and do the Board require any further information or assurance in relation to this?
2. What are the main risks and issues currently affecting CRN East Midlands?

Conclusion

1. This report provides an update on the recent progress of CRN East Midlands in supporting COVID-19 Urgent Public Health (UPH) research, including vaccine clinical trials. A summary of the COVID-19 research studies in the East Midlands is attached at Appendix 1 of the report. The report also provides a further update on the restart of NIHR research, a summary of our performance against the new CRN Performance Management Standards and an update on Host related matters which we want to make the Board aware of.
2. Our risks and issues register is attached at Appendix 3 to the report. Our highest risk relates to our ability to deliver specific COVID-19 protocols, considered as urgent public health (UPH) studies. We have now closed the risk related to delivering key elements of our Annual Plan. We have added a new risk that we will not deliver against the new NIHR Performance Standard relating to provider participation in NIHR portfolio research; however, the impact of this risk is minor as we are not being formally performance managed against this. The issue related to NUH employed staff and associated HR support has been resolved and we have formally closed this issue on the register.

Input Sought

We would welcome the Trust Board's input to review our report and provide any comments or feedback you might have.

For Reference

This report relates to the following UHL quality and supporting priorities:

1. Quality priorities

Safe, surgery and procedures	Not applicable
Safely and timely discharge	Not applicable
Improved Cancer pathways	Not applicable
Streamlined emergency care	Not applicable
Better care pathways	Not applicable
Ward accreditation	Not applicable

2. Supporting priorities:

People strategy implementation	Not applicable
Estate investment and reconfiguration	Not applicable
e-Hospital	Not applicable
More embedded research	Yes
Better corporate services	Not applicable
Quality strategy development	Not applicable

3. Equality Impact Assessment and Patient and Public Involvement considerations:

- What was the outcome of your Equality Impact Assessment (EIA)? N/A - This report does not relate to a business case/business decision making process.
- Briefly describe the Patient and Public Involvement (PPI) activities undertaken in relation to this report, or confirm that none were required - N/A
- How did the outcome of the EIA influence your Patient and Public Involvement ? - N/A as this report provides an update on the CRN and does not relate to a UHL business case/decision making.
- If an EIA was not carried out, what was the rationale for this decision?

4. Risk and Assurance**Risk Reference:**

Does this paper reference a risk event?	Select (X)	Risk Description:
Strategic: Does this link to a Principal Risk on the BAF?	N/A	
Organisational: Does this link to an Operational/Corporate Risk on Datix Register	N/A	
New Risk identified in paper: What type and description?		
None		

5. Scheduled date for the **next paper** on this topic: April 2021
6. Executive Summaries should not exceed **5 sides** My paper does comply

CRN East Midlands - Quarterly Board Update, 15 December 2020

1. Introduction

University Hospitals of Leicester (UHL) NHS Trust is the Host Organisation for the National Institute for Health Research (NIHR) Clinical Research Network East Midlands (CRN). UHL is contracted by the Department of Health and Social Care to take overall responsibility for the monitoring of governance and performance of the Network.

Our previous two quarterly Board reports were presented in the form of shorter, update papers, acknowledging that the Board has been focused on urgent priorities in response to COVID-19. As we approach the end of the year, we are keen to ensure the Board maintains appropriate visibility of the risks and issues affecting the Network; therefore, we have included some additional content in this report. This report provides an update on Urgent Public Health (COVID-19) research, restart of the NIHR research portfolio, CRN performance standards, risks & issues and Host related matters. Appended is a summary of COVID-19 research studies in the East Midlands, a table displaying the new CRN Performance Standards for 2020-21 and our current risks & issues register.

This report will be reviewed by the CRN East Midlands Executive Group in December 2020 and submitted to UHL Trust Board for review in January 2021.

2. Urgent Public Health (COVID-19) research including COVID-19 vaccine research

As of 7 December, we have supported the delivery of 30 Urgent Public Health (UPH) research studies, which have in total, recruited almost 20,000 participants in the East Midlands; across the UK, around 267,000 participants have been recruited into these UPH studies. A summary of the COVID-19 research studies in the East Midlands is attached at Appendix 1.

We are continuing to support the delivery of COVID-19 vaccine research studies in the East Midlands with collaboration across a range of healthcare systems. In Nottinghamshire, the Cripps Practice continues to deliver the COV002 (Oxford) study and this has now completed its recruitment phase. In Leicestershire, the NIHR Patient Recruitment Centre (PRC) based at LGH will be delivering vaccine research supported by primary care and community infrastructure. The site has recently started recruiting into the ENSEMBLE-2 commercial vaccine trial (Janssen). There has been significant media activity to raise the profile of this trial and to encourage people in Leicester and the surrounding areas to volunteer to take part. In Northamptonshire, a large primary care site, Lakeside, has been

delivering the first commercial COVID-19 vaccine study (Novavax), which has recently achieved its national target. The models in Lincolnshire and Derbyshire have a cross-sector focus, in readiness for further trials.

At present, and with the recent deployment of a licensed product, we are aware this is likely to impact on participant recruitment and retention. We are working closely with the NIHR national team, along with study Chief Investigators and Sponsors as to how to best support and advise participants.

As the region has been very successful with the recruitment of participants into UPH and vaccine studies, it will be important to ensure we maintain the support for these studies. It is critical that we contribute to the attainment of good quality data to help provide evidence for treatments and vaccines. We envisage that these studies, including those looking at longer term impacts of COVID-19, are likely to remain an important area of focus into 2021-22.

3. Restart of NIHR research

As a network, we have continued to work closely with trusts and other partners in relation to restarting paused non-COVID-19 research. Towards the end of Q2, LCRNs and Partner organisations completed a survey to indicate progress of reviewing paused studies either as a participating site or sponsor organisation. The survey showed variation in progress between organisations but also showcased that many organisations have put structures in place to review their portfolio on an ongoing basis. Progress varies across organisations/sectors, however, we have reported recruitment activity across all specialties, with the exception of oral and dental. For 2020-21, recruitment outside of UPH studies stands at approximately 10,500, with 393 studies currently open and recruiting (compared to 700 this time last year). The restarting of NIHR studies, will be largely dependent on both the progress of COVID/cases numbers, along with the restarting of NHS services.

4. CRN Performance Standards

Each year all Local Clinical Research Networks are expected to contribute to the NIHR CRN High Level Objectives, however, in this extraordinary year when the majority of Clinical Research has been paused due to the pandemic and focused upon supporting research on COVID-19 studies, it is unlikely that these objectives will be attained. Therefore core priorities for this year have been incorporated into a set of slimmed down Performance Management Standards for 2020-21. These have now been published and are attached to this report at Appendix 2. These are ambitions rather than targets. Our current performance is presented in the following table.

Objective	Ambition	Current East Midlands Performance
New Commercial Studies recruiting to time and target	70%	100%
Provider Participation in Research	(A) NHS Trusts - 100%	100%
	(B) Commercial Activity in NHS Trusts - 70%	44%
	(C) Research Activity at GP Practices - 45%	29%
	(D) Non-NHS Organisation Active Research Sites - 2250	207 (National measure)
Research Participant Experience	12,000 (National) 400 (East Midlands)	209
Urgent Public Health Study Set Up	9 Days	3 Days
Restart of studies paused due to the pandemic	80%	75%

5. Risks & Issues

Risks and issues are formally reviewed through the CRN Executive Group chaired by Andrew Furlong. A risks & issues register (Appendix 3) is maintained with risks discussed and mitigating actions agreed; this is shared periodically with the NIHR CRN Coordinating Centre (CRN CC). Due to the focus on COVID-19, and in the interests of brevity, we took a decision to omit appending our register in our previous two reports, however, we have reinstated it in this report.

Risks and issues are recorded on the register as follows:

- Risk #55 - Significant staff absence and/or diversion of staffing resource, across the East Midlands CRN funded workforce due to COVID-19 will impact on ability to deliver specific COVID-19 protocols, considered as urgent public health (UPH) studies. Our UPH portfolio has continued to grow over recent months and delivery of these research studies remains our main priority. We are continuing to work closely with sites to understand workforce issues and offer support where needed. This risk has a probability score of possible and impact score of major making this our highest risk at present.

- Risk #57 - Concern we will not be able to deliver key elements of our Annual Plan, such as expansion of social care research and other engagement work. We are now less concerned about this risk and we are not expected to formally report on our Annual Plan activities in the same way this year due to the continued focus on supporting COVID research. Consequently, the risk score has reduced significantly and we have now closed this risk on the risk register.
- Risk #58 - A new risk has been added that we will not deliver against NIHR Performance Standard on "Provider Participation" measures (B) & (C). The risk probability is scored as highly likely as we do not expect to meet this, however, the impact score is minor as we are not formally performance managed against this objective this year.
- Issue #01 - Ongoing issues in relation to NUH employed members of the core team, and associated HR support (non-Host) resulting in disproportionate amounts of time spent on staff management/support for these team members and concerns around how well both staff and managers are supported. This issue has largely been resolved and we have closed this on the issue register. Any residual actions related to this issue will be managed as part of our usual business processes.

6. Host related matters

We are awaiting information on the Host contract retendering process, which is expected to commence at the end of this financial year (or the start of the next financial year).

Office accommodation

Due to changes at the LRI site, the CRN are aware that our current accommodation at Knighton Street OPD will not be available from approx c.June 2021. We have been working with the UHL team responsible for reviewing accommodation requirements to supply details, however, we are keen to further discuss accommodation for the network teams in due course.

Host Audit, PWC

In line with our hosting contract, a three year cycle of audit is in place. PWC began the most recent audit in November 2020, with a conclusion/feedback still pending. There has been a slight delay due to changes in personnel (PWC). Feedback and any resulting actions will be shared in a future report.

If you have any questions or require any further information, please contact:

- Elizabeth Moss, Chief Operating Officer, elizabeth.moss@nihr.ac.uk or
- Professor David Rowbotham, Clinical Director, david.rowbotham@nihr.ac.uk or
- Carl Sheppard, Host Project Manager, carl.sheppard@nihr.ac.uk

COVID-19 Research Studies in the East Midlands

We are grateful to everyone involved in delivering and taking part in COVID-19 research in the East Midlands. These studies are currently taking place in our region:

<p>Accord 2</p> <p>Accelerating the development of new drugs to treat COVID-19 so they can be tested in large trials</p>	<p>GenOMICC</p> <p>Exploring whether certain genes can increase susceptibility to COVID-19 infection</p>	<p>PHOSP-COVID</p> <p>Conducting assessments to understand the impact of the virus on longer term health outcomes</p>	<p>SIREN</p> <p>Evaluating whether health workers who have had COVID-19 are protected from future episodes</p>	<p>What's the Story</p> <p>Determining how many children and young people have had COVID-19</p>
<p>ADAPT Sepsis</p> <p>Exploring whether the duration of antibiotic treatment for patients with sepsis can be reduced</p>	<p>ISARIC/CCP</p> <p>Determining how long people are infectious with COVID-19 and what puts them at risk</p>	<p>PRINCIPLE</p> <p>Analysing whether existing drugs could be used to help treat people with COVID-19 symptoms</p>	<p>STOPCOVID19</p> <p>Exploring whether a newly developed drug can help people with COVID-19</p>	<p>Vaccine Trials</p>
<p>BASIL C-19</p> <p>Exploring whether an intervention can prevent or improve depression symptoms in lockdown</p>	<p>Mermaids-ARI</p> <p>Analysing data to understand why some people become more ill than others with respiratory infections</p>	<p>RAPTOR C-19</p> <p>Assessing the effectiveness of different rapid tests to detect COVID-19</p>	<p>UKOSS</p> <p>Seeking to understand the impact of COVID-19 on pregnancy</p>	<p>A Phase 3 COVID-19 Vaccine Study</p> <p>This study is trialing a vaccine developed by Janssen-Cilag LTD</p>
<p>CLARITY</p> <p>Seeking to understand the impact of inflammatory bowel disease treatments on COVID_19</p>	<p>Neonatal Complications of Coronavirus Disease</p> <p>Investigating how COVID-19 affects babies</p>	<p>RECOVERY</p> <p>Exploring whether a range of treatments are more effective for patients than standard care</p>	<p>UK-REACH</p> <p>Assessing the impact of COVID-19 on ethnic minority healthcare workers</p>	<p>A trial of Recombinant Nanoparticle Vaccine</p> <p>This study is trialing a vaccine developed by Novovax INC</p>
<p>COPCOV</p> <p>Investigating whether two drugs are effective in preventing COVID-19 among frontline staff</p>	<p>NHS Check</p> <p>Exploring the impact of the pandemic on the work of NHS staff to inform approaches</p>	<p>RECOVERY RS</p> <p>Comparing the effectiveness of three ventilation methods for COVID-19 patients</p>	<p>VIVALDI</p> <p>Analysing how many staff and residents in care homes have been infected with COVID-19</p>	<p>Investigating a vaccine against COVID-19</p> <p>Trialing the Oxford vaccine. developed by AstraZeneca</p>
<p>Falcon</p> <p>Evaluating the diagnostic accuracy of in vitro diagnostic devices for monitoring infection</p>	<p>Pancovid</p> <p>Collecting data to understand the impact of COVID-19 during pregnancy</p>	<p>REMAP-CAP</p> <p>Analysing the effect of a number of drugs on patients with COVID-19 in intensive care</p>	<p>Virus Watch</p> <p>Using antibody tests to track how COVID-19 spreads and explore how to stop it</p>	<p>Key</p> <ul style="list-style-type: none"> Acute Primary Care Acute, mental health and community Trusts

Appendix 2

Revised High Level Objectives for 2020/21

The below Table replaces section B.4. 'LCRN Performance Indicators' in the Performance and Operating Framework 2020/21, Version 1.0, 17 April 2020. These indicators will be referred to as CRN Performance Standards for 2020/21.

Table 1 – NIHR CRN High Level Objectives

Objective		Measure*	Ambition	Level	Note
Efficient Study Delivery	Deliver NIHR CRN Portfolio studies to recruitment target within the planned recruitment period	(C) Proportion of new commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed CRN sites	70%	CRN	1
Provider Participation	Widen participation in research by enabling the involvement of a range of health and social care providers	(A) Proportion of NHS Trusts recruiting into NIHR CRN Portfolio studies	99%	LCRN / CRN	2
		(B) Proportion of NHS Trusts recruiting into NIHR CRN Portfolio commercial contract studies	70%	LCRN / CRN	3
		(C) Proportion of General Medical Practices recruiting into NIHR CRN Portfolio studies	45%	LCRN / CRN	4
		(D) Number of non-NHS sites recruiting into NIHR CRN Portfolio studies	2,250	CRN	5
Participant Experience	Demonstrate to people taking part in health and social care research studies that their contribution is valued	Number of NIHR CRN Portfolio study participants responding to the Participant Research Experience Survey, each year	12,000	LCRN / CRN	6

Urgent Public Health	Minimise set-up times for NIHR CRN UPH Portfolio studies	Study site set-up time (working days)	9	CRN	7
Restart	Restart the NIHR CRN Portfolio paused by Sponsors and Sites due to COVID-19	(A) Percentage of paused commercial contract studies that are no longer paused at 31 March 2021	80%	CRN	8
		(B) Percentage of paused non-commercial studies that are no longer paused at 31 March 2021	80%	CRN	9

* The letter in parenthesis, e.g. (A), denotes the relationship between the measure in the Revised High Level Objectives for 2020/21 (i.e. this version) and the superseded version of High Level Objectives for 2020/21 (i.e. the previous version). Where there is more than one Measure per Objective, and the Measure does not start with (A), this indicates that previous Measure(s) associated with the Objective have been removed. Where there is a single Measure per Objective, no parenthesis is present/required.

Ambition Notes

1. Efficient Study Delivery (C). Ambition value 70%. This is a new ambition for 2020/21. 'New' indicates opened on or after 1 April 2020 and closed to recruitment on or before 31 March 2021
2. Provider Participation (A). Ambition value 99%, unchanged from 2019/20 Ambition value
3. Provider Participation (B). Ambition value 70%, unchanged from 2019/20 Ambition value
4. Provider Participation (C). Ambition value 45%, unchanged from 2019/20 Ambition value
5. Provider Participation (D). Ambition value 2,250, the 2019/20 out-turn value plus 5%
6. Participant Experience. Ambition value 12,000, an increase of 2,000 on the 2019/20 Ambition value

7. Urgent Public Health. Ambition value 9 working days. This is a new HLO introduced as a revision for 2020/21. The Ambition value was determined by experience setting up Urgent Public Health Studies earlier in this reporting year, under two working weeks being both ambitious and feasible

8. Restart (A). Ambition value 80%. This is a new HLO introduced as a revision for 2020/21. The denominator, the number of 'Paused' studies, is the number of studies recorded by the CRNCC as 'Paused' on 18 May 2020. 'No longer paused' implies an update to the study status from 'Paused' to another status

9. Restart (B). Ambition value 80%. This is a new HLO introduced as a revision for 2020/21. The denominator, the number of 'Paused' studies, is the number of studies recorded by the CRNCC as 'Paused' on 18 May 2020. 'No longer paused' implies an update to the study status from 'Paused' to another status

University Hospitals of Leicester NHS Trust
Owner of Risk Register: Executive Group

PRE-RESPONSE (INHERENT)										POST-RESPONSE (RESIDUAL)							
Risk ID	Primary category	Date raised	Risk owner	Risk Description (event)	Risk Cause and Effect	Probability	Impact	Value (PxI)	Proximity	Response Actions	Action owner(s)	Action status	Probability	Impact	Value (PxI)	Risk status (open or closed date)	Trend (since last reviewed)
R055	Services	Mar-20	COO	Significant staff absence and/or diversion of staffing resource, across the East Midlands CRN funded workforce due to COVID-19 will impact on ability to deliver specific COVID-19 protocols, considered as urgent public health studies	<p>Cause: COVID-19 pandemic will lead to staff absence (illness, self-isolation or caring for family members) or other reduced capacity in the workforce due to movement to clinical & supporting duties</p> <p>Effect: Unable to deliver priority Public Health COVID-19 research studies in all necessary sites</p>	4	4	16	Mar-20	Communicate regular updates and advice to core team staff and partners	COO / Comms Lead	4	3	4	12	Open	Static
										Ensure national and Host guidance is followed	COO / all	4					
										Implement and follow CRNEM Urgent Public Health Plan	COO, RDM (D6)	4					
										Report any disrupted research studies to CRNCC	COO / all	4					
										Established regional vaccine group to support delivery of UPH vaccine studies with broad stakeholder representation. Group informs regional planning approach as a collective, with strong partner engagement.	IOM / BDOM	4					
										Regional workforce planning for vaccines, leadership through the above group	WFD Lead/ BDOM	4					
										Successful in application to national VTF funding for vaccines research studies	DCOO	4					
										Continued close communication with sites to understand workforce issues and support where needed	IOM / BDOM	4					
Review of UPH study performance through study leads	DCOO	4															
R058	Performance	Nov-20	DCOO	<p>CRN EM will not deliver against NIHR Performance Standard on "Provider Participation" measures (B) & (C)</p> <p>(B) Proportion of NHS Trusts recruiting into NIHR CRN Portfolio commercial contract studies (ambition 70%)</p> <p>(C) Proportion of General Medical Practices recruiting into NIHR CRN Portfolio studies (ambition 45%)</p>	<p>Cause: Impact of COVID-19 - prioritisation of UPH studies, low number of suitable studies for Healthcare, Partnership & Community Trusts, challenging studies to set-up at some sites. Closure of high recruiting study in primary care.</p> <p>Effect: We are not formally performance managed against this objective this year, however, the effect of not meeting this standard is that the lack of pipeline commercial studies would impact on the availability of novel treatments for patients across the region.</p>	5	2	10	Mar-21	Increase knowledge of new studies via the Expression of Interest Website	Divisional Teams	4	5	2	10	Open	New
										Supporting partners to identify studies which could contribute to their pipeline for 2021/22	Divisional Teams/ Senior Team Link	1					
										Support collaborative working between partner organisations, such as community Trusts and Acute Trusts to support the delivery of studies.	Divisional Teams/ IOM	1					
R057	Performance	May-20	COO	Concern we will not be able to deliver key elements of our Annual Plan, such as expansion of social care research and other engagement work	<p>Cause: Our current priority is to support urgent COVID-19 research so capacity to deliver other work is reduced. Also, our partners and wider stakeholders will be focussed on the COVID-19 response and opportunities for engaging in broader work will be limited. Additionally social care services will also be being delivered in very different ways which is likely to limit our ability to engage with and work across this sector.</p> <p>Effect: Non-compliance with performance indicators, delays to our current plans and knock-on effect for future plans (expansion of research, engagement etc.)</p>	4	3	12	May-20	Establish working group to reassess Annual Plan and identify which projects would be feasible to deliver or revise if needed - COO, DCOO & HPM met to review this	COO/HPM	5	2	2	4	Closed 9.12.20	Decreased
										Consider submission of revised plan - not required	COO/HPM	5					
										Seek advice and guidance from CRNCC, including any requirements on reporting non-compliance	COO/HPM	5					
										Support local implementation of RESTART Programme	COO/HPM	4					
										Continue to engage with colleagues across social care environment, receive updates as to appropriate action and revise plans, as needed.	HPM/ COO/ ROM (div 2&5)	4					
										Working on proposals for Social care investments/posts, with colleagues in Lincoln	ROM/ RDM (Div 2&5)	4					
										Recently received new funding for PH posts, currently in development	ROM/ RDM (Div 2&5)	4					

SCORING:

PROBABILITY	IMPACT				
	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Highly Likely (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Highly Unlikely (1)	1	2	3	4	5

- 1-5 GREEN = LOW*
- 6-11 YELLOW = MEDIUM
- 12-19 AMBER = HIGH
- 20-25 RED = EXTREME

*Only risks with an Inherent Risk of 6 or above are recorded on this Risk Register
 * Risks with a scoring of 12 and above should be monitored and escalated

Action RAG Status Key:

Complete	5
On Track	4
Some Delay – expected to be completed as planned	3
Significant Delay – unlikely to be completed as planned	2
Not yet commenced	1

CRN East Midlands Issues Register

Date Last Reviewed : 09.12.2020

Issue ID	Issue Type	Date Raised	Owner	Description	Severity	Priority	Actions	Action Owners	Action status	Issue status
I01 (was R045)	Performance	Jan 2019	COO	Ongoing issues in relation to NUH employed members of the core team, and associated HR support (non-HOST) resulting in disproportionate amounts of time spent on staff management/support for these team members and concerns around how well both staff and managers are supported. This also impacts on our overall ability to focus on other aspects of CRN delivery under the Host contract	Minor	Medium	Quarterly meetings with Senior HR (UHL & NUH) & CRN	COO	5	CLOSED
							Monthly meetings with operational HR (NUH) & CRN	COO	5	
							HR policy training provided to staff	COO & DCOO	5	
							To raise options with staff and or Senior HR rep at NUH, as and when appropriate	COO & DCOO	1	

KEY	
Severity	Priority
Minor	Low
Moderate	Medium
Major	High
Catastrophic	Critical

Action RAG Status Key:

Complete	5
On Track	4
Some Delay – expected to be completed as planned	3
Significant Delay – unlikely to be completed as planned	2
Not yet commenced	1