

## BOARD OF DIRECTORS MEETING

<b>Agenda Item</b>	<b>P1/014/19</b>	<b>Date: 30th January 2019</b>						
<b>Subject /title</b>	<b>Planning for Brexit</b>							
<b>Author</b>	<b>Helen Poulter-Clark</b>							
<b>Responsible Director</b>	<b>Sheila Lloyd</b>							
<b>Executive summary and key issues for discussion</b>								
<p>There remains a great deal of uncertainty regarding the potential of the final “Brexit deal.” This paper is written on assumption that the UK will go ahead with Brexit on the 29<sup>th</sup> of March. There is potential impact to The Clatterbridge Cancer Centre (CCC) of a “no deal Brexit” deal in the short term as well medium to long term impact with respect to areas such as CCC workforce and strategy.</p>								
<b>Strategic context and background papers (if relevant)</b>								
See Brexit Update Paper								
<b>Recommended Resolution</b>								
<p>The Board is asked to</p> <ul style="list-style-type: none"> <li>• Note CCC specific risks identified and mitigation proposed.</li> <li>• Agree the development of communications for patients, staff and the C&amp;M system.</li> <li>• Confirm if they are funding applications for EU settlement scheme.</li> </ul>								
<b>Risk and assurance</b>								
Risks identified on DATIX								
<b>Link to CQC Regulations</b>								
<b>Resource Implications</b>								
<b>Key communication points (internal and external)</b>								
<b>Freedom of Information Status</b>								
<p>FOI exemptions must be applied to specific information within documents, rather than documents as a whole. Only if the redaction renders the rest of the document non-sensical should the document itself be redacted.</p> <p><b>Application Exemptions:</b></p> <ul style="list-style-type: none"> <li>• <b>Prejudice to effective conduct of public affairs</b></li> <li>• <b>Personal Information</b></li> <li>• <b>Info provided in confidence</b></li> <li>• <b>Commercial interests</b></li> <li>• <b>Info intended for future publication</b></li> </ul>	<p>Please tick the appropriate box below:</p> <table border="1"> <tr> <td><input checked="checked" type="checkbox"/></td> <td><b>A. This document is for full publication</b></td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>B. This document includes FOI exempt information</b></td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>C. This whole document is exempt under FOI</b></td> </tr> </table> <p><b>IMPORTANT:</b></p> <p>If you have chosen B above, highlight the information that is to be redacted within the document, for subsequent removal.</p> <p>Confirm to the Trust Secretary, which applicable exemption(s) apply to the whole document or highlighted sections.</p>		<input checked="checked" type="checkbox"/>	<b>A. This document is for full publication</b>	<input type="checkbox"/>	<b>B. This document includes FOI exempt information</b>	<input type="checkbox"/>	<b>C. This whole document is exempt under FOI</b>
<input checked="checked" type="checkbox"/>	<b>A. This document is for full publication</b>							
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<input type="checkbox"/>	<b>C. This whole document is exempt under FOI</b>							

Equality & Diversity impact assessment		
Are there concerns that the policy/service could have an adverse impact because of:	<b>Yes</b>	<b>No</b>
Age		<b>X</b>
Disability		<b>X</b>
Sex (gender)		<b>X</b>
Race		<b>X</b>
Sexual Orientation		<b>X</b>
Gender reassignment		<b>X</b>
Religion / Belief		<b>X</b>
Pregnancy and maternity		<b>x</b>
If YES to one or more of the above please add further detail and identify if full impact assessment is required.		
<b>Next steps</b>		
<b>Appendices</b>		
N/A		

### Strategic Objectives supported by this report

Improving Quality	<b>x</b>	Maintaining financial sustainability	<b>x</b>
Transforming how cancer care is provided across the Network	<b>x</b>	Continuous improvement and innovation	<b>x</b>
Research	<b>x</b>	Generating Intelligence	<b>x</b>

### Link to the NHS Constitution

<b>Patients</b>		<b>Staff</b>	
Access to health care		<i>Working environment</i> Flexible opportunities, healthy and safe working conditions, staff support	<b>x</b>
Quality of care and environment	<b>x</b>	<i>Being heard:</i> • Involved and represented • Able to raise grievances • Able to make suggestions • Able to raise concerns and complaints	<b>x</b>
Nationally approved treatments, drugs and programmes			
Respect, consent and confidentiality			
Informed choice		Fair pay and contracts, clear roles and responsibilities	<b>x</b>
Involvement in your healthcare and in the NHS		Personal and professional development	<b>x</b>
Complaint and redress	<b>x</b>	Treated fairly and equally	<b>x</b>

## **CCC Business Continuity Update - Brexit**

January 2019

Helen Poulter-Clark – Chief Pharmacist

### **Introduction**

At time of writing, there remains a great deal of uncertainty regarding the potential of the final “Brexit deal.” This paper is written on assumption that the UK will go ahead with Brexit on the 29<sup>th</sup> of March. There is potential impact to The Clatterbridge Cancer Centre (CCC) of a “no deal Brexit” deal in the short term as well medium to long term impact, with respect to areas such as CCC workforce and strategy.

### **Governance Arrangements**

Business Continuity Planning SRO: Sheila Lloyd – Director of Nursing and Quality and Accountable Emergency Officer (AEO)

CCC Brexit Senior Risk Officer (SRO): Helen Poulter-Clark – Chief Pharmacist

CCC Emergency Preparedness Officer: Steve Povey - H&S Adviser & Emergency Preparedness Officer

CCC overview is via the Governance & compliance sub-committee

NHS England EPRR (Emergency Preparedness, Resilience and Response) are acting as the conduit for information and are taking part in the teleconferences at national level. To disseminate information, Brexit/EU Exit is a standing agenda item for the LHRP (Local Health Resilience Partnership) Strategic and Practitioners meetings.

The NHSE Delivery Manager at EPRR has been seconded to be the Brexit lead for the north and there is a dedicated Cheshire and Mersey Brexit lead at EPRR. Cheshire Local Resilience Forum are holding SCG meetings (Strategic Coordination Group) monthly in Jan & Feb then weekly through March. NHS represented by NHS ENGLAND head of EPRR, Jim Deacon.

Strategic meetings are attended by the Trust AEO (EPO deputises as required) and Practitioners meetings are attended by the trust EPO.

## Areas of focus

### 1. Medicines

- Procurement of medicines by The Clatterbridge Pharmacy Ltd (CPL.) CPL do not have a central store and operate “Just in Time”

Issue	Action	Responsibility	Timescale	Risk Register (Y/N)	Financial Impact (Y/N)
Potential for impact on access to medicines	Medicine overview via the Quality & Safety sub-committee,  Increase buffer stock n.b. this is not stockpiling-parity with other trusts in terms of levels.	HPC	Feb / March 2019	Y  Sept 2018 – Risk Score 16	CPL / CCC – 300K contingency for increased buffer stock

### 2. Clinical Trials

- MHRA (Medicines and Healthcare products Regulatory Agency) manage clinical trials nationally
- Sponsor is responsible for all aspects of clinical trial management and oversight including drug supply and safety reporting
- All EU Directives transposed into UK law, except for any new Directive - MHRA will aim to align with this post-BREXIT
- Currently a Sponsor or their ‘Legal Representative’ should be based in the EU or EEA; the MHRA will be seeking to preserve this position

Issue	Action	Responsibility	Timescale	Risk Register (Y/N)	Financial Impact (Y/N)
CCC acts as participating site and Sponsor respectively	Align to all processes as instructed by Sponsor  Maintain view and gain updates from MHRA	MM	Mar 2019	Y  October 2018 – Risk Score 9	N

### 3. CCC as a Sponsor for International Studies

- Contract organisations or Lead Sites to act under a form of 'Co-Sponsorship' arrangement within the host country to deal with regulatory aspects according to that country's legislation
- Drug supply contracts and distribution assured with industry funders for CCC-Sponsored studies
- No notifications from funder or international sites that change status

Issue	Action	Responsibility	Timescale	Risk Register (Y/N)	Financial Impact (Y/N)
CCC as sponsor for international research studies	Maintain contract negotiations and communication with contract organisations, Liverpool Health Partners contracts officer involved in all aspects to advise	MM	Mar 2019	Y  October 2018 – Risk Score 9	N

	Progress to set-up with advice sought from MHRA				
	Updates through Research Governance Committee and reporting to Quality & Safety sub-committee				

#### 4. Workforce

- Focus has been on the risk of losing workers and ensuring that those staff who are EU Nationals apply for settlement. EU citizens, will be able to apply to the EU Settlement Scheme to continue living in the UK after 30 June 2021. If their application is successful, they will get either settled or pre-settled status. Some staff may be able to stay in the UK without applying - for example, if they are an Irish citizen or have indefinite leave to remain (ILR).
- The EU Settlement Scheme will open fully by 30 March 2019. The deadline for applying will be 30 June 2021. The fee to apply will be £65. There is no requirement for employers to pay for settlement applications, however some organisations have chosen to do so and nationally Unison have called on all public sector employers to pay the fees.
- If applicants successfully apply to the EU Settlement Scheme they can continue to live and work in the UK after 31 December 2020.

Settled Status		Pre Settled Status	
Eligibility	Rights	Eligibility	Rights
<p>Applicants must:</p> <ul style="list-style-type: none"> <li>started living in the UK by 31 December 2020</li> <li>lived in the UK for a continuous 5-year period ('continuous residence')</li> </ul>	<p>Able to:</p> <ul style="list-style-type: none"> <li>stay in the UK for as long as you like</li> <li>apply for British citizenship, if you're eligible</li> </ul>	<p>If applicants do not have 5 years' continuous residence, they will usually get 'pre-settled status'.</p> <p>Applicants can stay in the UK for a further 5 years from the date you get pre-settled status.</p>	<p>Spend up to 2 years in a row outside the UK without losing pre-settled status, but MUST maintain continuous residence if they want to qualify for settled status.</p> <p>Able to:</p>

	<ul style="list-style-type: none"> <li>•work in the UK</li> <li>•use the NHS</li> <li>•enrol in education or continue studying</li> <li>•access public funds such as benefits and pensions, if you're eligible for them</li> <li>•travel in and out of the UK</li> </ul>		<ul style="list-style-type: none"> <li>•work in the UK</li> <li>•use the NHS</li> <li>•enrol in education or continue studying</li> <li>•access public funds such as benefits and pensions, if you're eligible for them</li> <li>•travel in and out of the UK</li> </ul>
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- No tangible evidence of impact of final Brexit agreement until the future. The Government is proposing a single immigration system that will treat workers from the EU the same way as those from non EU countries
- Key risk area as this is a significant change as it will be the end to the freedom of movement and may deter skilled workers from applying through the immigration system. We do not yet have any evidence of what the reduction in the number of EU workers allowed to the UK will be.
- CCC currently do not have particularly large numbers of EU workers (41), however with the expansion to Liverpool it may have an impact upon the pool of candidates available for roles in the future. The cost of applying for immigration may also have an impact on the number of candidates applying for key roles from the EU.
- There is currently no detail of the pay threshold that candidates must earn to qualify enough points to apply for immigration status. It was initially proposed that the current non EU immigration threshold of £30,000 per annum would be imposed in the future on applicants from the EU. However, the government has since confirmed in December 2018 that there will be further consultation on this matter and priority will be given to highly skilled workers.
- The UK Terms and Conditions of employment are linked to EU policies and procedures e.g. working time regulations. Future changes to employment legislation may have an impact on highly skilled workers deciding to work and live in the UK.

Issue	Action	Responsibility	Timescale	Risk Register (Y/N)	Financial Impact (Y/N)
Potential impact of attracting and sourcing replacements for current employees that may make the decision to leave the UK	Monitor and review the number of applications we are receiving from EU and report on the variance against regional and national statistics that are available. Giving consideration to the timescales involved and the expansion to Liverpool.	JG	On-going to June 2021	N	Y (value not known)
	Continue to update relevant committees on changes to immigration system and settlement agreements that have an impact upon our workforce planning and employee relations.	JG	Mar 2019	N	N
	Review workforce plans to consider the number of roles that are currently undertaken by EU workers and the risk of being able to backfill those roles.	JG	Mar 2019	Y	N
	Provide up to date information on the number of our employees that have/will apply for settlement by 2020	JG	Sept 2019	N	N
	Write to all EU workers advising them to apply for settlement status during the NHS Pilot programme running from 29th Nov to 21st Dec.	JG	Feb 2019	N	N



	Monitor retention within particular staff groups and report to Recruitment and Retention Steering Group	KG	Sept 2019	Y	Y
	Attraction strategies to take into account financial implications for the Trust if we need to support visa costs for key roles.	KG	Sept 2019	N	Y

## 5. CCC Subsidiaries (PharmaC, PropCare and Clatterbridge Clinic)

- PropCare has reviewed the potential impact of Brexit on its two main areas of operations, i.e. the delivery of the new Liverpool Cancer Centre and the estates management of the Wirral and Aintree sites, for the period immediately after the 29th March 2019 should a no deal be implemented by the UK Government. Having discussed this with our key suppliers and internally within our management team we are not aware of any significant issues that would arise that would significantly impact either the build of the new hospital or the provision of estates services to CCC by PropCare and its suppliers
- PharmaC-see medicines section

Issue	Action	Responsibility	Timescale	Risk Register (Y/N)	Financial Impact (Y/N)
Risk to CCC as result of change in strategy of partners  Private Patient Joint Venture	To engage with partners to understand Brexit risks	PPJV Board	Mar 2019	N	Unknown

## 6. Imaging

- Unlike other medicines cannot have buffer for radiopharmaceuticals, any new border arrangements may impact the time a delivery can be made and the activity delivered. This could impact on scanning capacity levels
- There is potential for increased cost for the radiopharmaceuticals and delivery costs as some contrast agents and related consumables come in from Europe
- Most parts for major equipment come in from Europe and any new border arrangements may impact the time a delivery can be made. As result equipment down time may be increased
- There is potential for increased cost for the maintenance contracts as this will passed to the customer

Issue	Action	Responsibility	Timescale	Risk Register (Y/N)	Financial Impact (Y/N)
Potential for increased time and cost of the purchase of contrast agents, radiopharmaceuticals and consumables to be passed to the customer	For the supply of radiopharmaceuticals no known controls can be put in place	Claire Atkinson / Linda Williams	March 19	Y	Unknown
	A contingency plan for possible alternative imaging examinations will be investigated	Claire Atkinson / Linda Williams		Risk assessment undertaken Sept 2019 – Risk Score 16	
	Work with manufacturers regarding their own business continuity planning for equipment parts	For all of below; Imaging -Susan Wright	March 19	No	Unknown

	<p>Work with Pharmacy to establish the right stock levels for contrast agents</p> <p>Review storage facilities for contrast agents</p> <p>Investigate ability to procure from contrast agents alternate providers</p>	<p>/Helen Purslow</p> <p>RT - Lynn Bell/ Louise Bunby</p>			
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## 7. Contracts and Procurement

- NHS Trusts have been requested to self-assess and review contracts that may be impacted by a 'no deal' EU exit. Trusts are expected to carry out a contract review of their third party procurement spend. It is recommended that Trusts apply the NHS Self-Assessment Methodology to carry out a triage of third party procurement spend, and then to carry out a deep dive analysis of those contracts deemed to be higher risk to the provision of healthcare services at 29 March 2019.
- Contracts, categories and suppliers managed centrally by DHSC, are out of scope of the Trust Self-Assessment.
- Key categories affected may be:
  - Medical devices and clinical consumables (MDCC)
  - Capital equipment and spares parts
  - Hotel Services including cleaning products (not bought through NHS Supply Chain).
- Conclusion of the self-assessment and results of the deep dive analysis, along with the proposed mitigation activities have been submitted to DHSC on 30 November 2018.

Issue	Action	Responsibility	Timescale	Risk Register (Y/N)	Financial Impact (Y/N)
Contract review of contracts impacted by no deal EU exit	<p>Self-assessment on all our suppliers completed and submitted 30 November. As a result of this exercise an additional list of suppliers have been added to the list that will be centrally managed including Varian, BOC and AAH.</p> <p>NHS supply chain have also increased their stock holding and storage facilities for a no deal E U exit.</p> <p>Heads of services need to be contacting key suppliers to ensure continuity of supply i.e. any suppliers that are not on the centrally managed list.</p>	<p>PC</p> <p>PC</p> <p>All managers</p>	N/A	No	No

### Next Steps

Agree communication for patients, staff and the C&M system. Communication for patients needs to include all Brexit aspects-not just medicines. Internal communication to staff regarding commonly asked questions.

CCC to confirm if they are funding applications for EU settlement scheme. Total cost to the Trust to fund 41 applications at £65 each would be £2665