Clinical Risk Management: its Application in the Manufacture of Health IT Systems – DCB0129

Cyres Cinergy Software

This statement has been prepared for the benefit of current and prospective customers and partners of Cyres Limited and relates to the Cinergy software product developed by Cyres.

Terminology

In this document, the following terms have the following meanings:

"Cyres"	Cyres Limited
"Cyres Cinergy"	Cyres Cinergy cytology and colposcopy statistical reporting software
"DCB0129"	Information standard relating to *Clinical Risk Management: its Application in the Manufacture of Health IT Systems* published by the Data Coordination Board and approved by the Department of Health and Social Care under s250 Health & Social Care Act 2012 – published 02/05/2018, as amended
"the Guidance"	The NHS Digital guide to the applicability of DCB0129 - *https://digital.nhs.uk/services/clinical-safety/applicability-of-dcb-0129-and-dcb-0160* - published 27/05/2022

In response to DCB0129 and the Guidance, Cyres has undertaken a full review of its software and the operations it conducts.

Cyres Cinergy - Overview

- Cyres Cinergy has been in use within the NHS and has been subject to continuous development in response to evolving user requirements over a period of more than 15 years.

Cyres Limited, 33 Back Street, South Creake, Fakenham, Norfolk NR21 9PG
Tel: 01223 655 466 | Email: info@cyres.co.uk | www.cyres.co.uk
Registered office: Knights Lowe, Eldo House, Kempson Way, Suffolk Business Park, Bury St Edmunds, Suffolk IP32 7AR Registered in England & Wales No. 4321140

- Cyres Cinergy is supplied without any data and is designed to be used by health care organisations to connect to their own data sources and to provide high-level statistical data analysis and reports.
- The reports generated include standard periodic key performance indicators which organisations have a statutory obligation to submit to SQAS and NHSE.
- The software can also produce a range of customisable audit and performance reports.
- By the nature of the type of data with which Cyres Cinergy is designed to be used, the electronic information it generates is retrospective rather than real-time or near-real-time.
- Cyres Cinergy is designed and developed to deliver the reporting functionality outlined above. This is made clear to customers at the outset and is reflected in the initial training and follow-up support provided to users.
- The software is not designed or intended to be used for specific clinical purposes or for use in relation to the care or treatment of individual patients.

DCB0129 – "Health IT Systems" and "Manufacturers"

- DCB0129 defines a "Health IT System" as a "product used to provide electronic information for health or social care purposes".
- Cyres Cinergy is a product designed and used to provide electronic information for health care organisations. However, it provides no clinical functionality and is not designed to be used for delivering "health care" as such.
- As the organisation responsible for the design, development and supply of the software, Cyres is the "Manufacturer" of Cyres Cinergy for the purposes of DCB0129.

DCB0129 – "Medical Devices"

- Cyres Cinergy is not software necessary for the functional implementation or proper application of any instrument, apparatus, appliance, material or other article intended to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease.
- It therefore does not fall within the scope of DCB0129 as a "Medical device".

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Applicability of DCB0129 to Cyres Cinergy

- With specific reference to Step 3 of the Guidance, Cyres Cinergy is not designed to be "used to influence, support or manage the real-time or near-real-time direct care of patients/service users".
- As a product designed to be used for population-level data analysis and reporting, Cyres Cinergy therefore does not fall within the scope of DCB0129.
- DCB0129 is therefore not legally mandated.

NHS Digital Recommended Adoption of DCB0129

- It is noted that NHS Digital recommends in the Guidance that DCB0129 is adopted in all circumstances where digital products are developed or deployed to support health services. Moreover, adoption is strongly recommended "especially where such products are used to make care commissioning decisions".
- Cyres takes all matters relating to its legal and contractual obligations extremely seriously and ensures that it has all appropriate policies, procedures, training, insurance and resources in place.
- After careful consideration, Cyres has concluded that it would not be appropriate to follow this recommendation in relation to Cyres Cinergy, for the following reasons:

1. **Scope of DCB0129**
   - As stated above, the functionality and intended use of of Cyres Cinergy places it outside the scope of DCB0129.

2. **Clinical Scope**
   - The *Implementation Guidance* for DCB0129 (v3.2 at 4.2) defines "Clinical Scope" in the context of defining the boundary of a clinical risk assessment. It states that "Clinical scope is the extent of the functionality that is provided within the Health IT System that can be used to support or influence the administration of healthcare to a patient".

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- Cyres Cinergy is designed with a very specific functionality which does not extend to any clinical process. Although some users might be clinicians, it is not intended for clinical use and its functionality is not designed to be used to support or influence the administration of healthcare to a patient.
- The preamble to DCB0129 itself, at 1.1, states that "the extent of clinical risk management needs only to be commensurate with the scale, complexity and level of clinical risk associated with the deployment".
- Even if Cyres Cinergy fell within the definition of a "Health IT System", it does not offer any "clinical scope" as defined above.
- Given this lack of clinical scope, Cyres is not in a position to undertake any identification of hazards to patients or assessment of clinical risks.
- Therefore, it is neither possible nor necessary to adopt and implement the clinical risk management framework contained in DCB0129.

3. Care Commissioning Decision-Making

- Cyres Cinergy is not designed or intended to be used as a tool for care commissioning decision-making.
- The software is primarily designed to enable health service providers to comply with their statutory statistical performance reporting obligations, with additional functionality to facilitate analysis of such performance. Any health organisation seeking to use Cyres Cinergy for care commissioning decision making would be acting outside the intended use of the software.
- Any health organisation seeking to utilise Cyres Cinergy beyond its intended use would have to rely on its own clinical risk management procedures under the Data Coordination Boards' standard DCB0160 (*Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems*).

The contents of this statement will be subject to review at appropriate intervals and any updates will be available on the company website.

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