

# The Digital Technology Assessment Criteria for Health and Social Care (DTAC)

<b>Product:</b>	<b>Cyres Cinergy</b>	<b>Developer:</b>	<b>Cyres Limited</b>	<b>Reviewed:</b>	<b>26/06/2024</b>
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## A. Company Information

Code	Question	Answer
A1	Name of company	Cyres Limited
A2	Name of product	Cyres Cinergy
A3	Type of product	Software
A4	Name and job title of the individual who will be the key contact	Sebastian Brunt, Managing Director
A5	Key contact's email address	<a href="mailto:s.brunt@cyres.co.uk">s.brunt@cyres.co.uk</a>
A6	Key contact's phone number	01223 655466
A7	Registered address of company	Eldo House, Kempson Way, Suffolk Business Park, Bury St Edmunds, Suffolk IP32 7AR
A8	Country of registration	England & Wales
A9	Companies House registration number	4321140
A10	Last assessment from the Care Quality Commission (CQC)?	Not Applicable

## B. Value Proposition

Code	Question	Answer
B1	Who is this product intended to be used for?	Those requiring high-level statistical data analysis and reports in relation to cytology / colposcopy
B2	Provide a clear description of what the product is designed to do and of how it is expected to be used	The product is designed to enable NHS trusts to generate statistical reports, based on their own data sources, for analysis and for mandatory performance monitoring reporting
B3	Describe clearly the intended or proven benefits for users and confirm if / how the benefits have been validated	<p>Cyres Cinergy was evaluated and approved by PHE and then NHSE who have subsidised the rollout of the product for over 15 years as they believe that:</p> <ul style="list-style-type: none"> <li>• it saves huge amounts of staff time in that mandatory reports can be generated at the click of a button</li> <li>• the standardization of data across all sites enables performance to be monitored and checked on a like-for-like basis; and</li> <li>• any queries can be quickly and easily investigated using in-built drill-down facilities</li> </ul>
B4	<p>Please attach one or more user journeys which were used in the development of this product</p> <p>Where possible please also provide your data flows</p>	<p>The product was originally developed over 15 years ago in close consultation with specialist NHS staff</p> <p>Data does not “move through the product”. Instead, the product analyses a block of data <i>in situ</i> and generates analytics and reports based on the data</p>

## C. Technical Questions

### C1 - Clinical Safety

Code	Question	Answer	Comments
C1.1	Have you undertaken Clinical Risk Management activities for this product which comply with DCB0129?	No.  Outside the scope of DCB0129	<p>The product provides population-level statistical analysis and reports in relation to retrospective data</p> <p>It is not designed or intended to be used to influence, support or manage the real-time or near-real-time direct care of patients</p> <p>The product cannot be used for specific clinical purposes or for use in relation to the care or treatment of individual patients</p> <p>The product does not fall within the scope of DCB0129</p> <p>For further information, please see the company statement on DCB0129, attached</p>
C1.1.1	Please detail your clinical risk management system	Not applicable – see C1.1	
C1.1.2	Please supply your Clinical Safety Case Report and Hazard Log	Not applicable – see C1.1	
C1.2	Please provide the name of your Clinical Safety Officer (CSO), their profession and registration details	Not applicable – see C1.1	

C1.3	If your product falls within the UK Medical Devices Regulations 2002, is it registered with the Medicines and Healthcare products Regulatory Agency (MHRA)?	Not applicable	
C1.4	Do you use or connect to any third-party products?	No	

## C2 - Data Protection

Code	Question	Answer	Comments
C2.1	If you are required to register with the Information Commissioner, please attach evidence of a current registration.	Provided	See current ICO registration certificate attached  We are only required to register in relation to internal staff data and internal contact data of suppliers and customers  We do not control or process data with the product
C2.2	Do you have a nominated Data Protection Officer (DPO)?	We do not need one	We do not fall within the categories where a DPO is a requirement  In particular, we do not process health data
C2.2.1	If you are not required to have a DPO please attach a completed self-assessment showing the outcome from the Information Commissioner and your responses which support this determination.	Provided	See ICO self-assessment attached

C2.3	Does your product have access to any personally identifiable data or NHS held patient data?	No	<p>The product does not hold or store any data</p> <p>We do not have access to any personally identifiable data or NHS held patient data or engage in data processing on behalf of NHS trusts</p> <p>The product is used by NHS trusts to analyse their own datasets</p> <p>For further details, please see company statement on GDPR attached.</p>
C2.4	Please confirm your risk assessments and mitigations / access controls / system level security policies have been signed-off by an accountable officer	Confirmed	
C2.5	Please confirm where you store and process data (including any third-party products your product uses)	UK only	We only store and process internal data relating to staff and commercial contacts
C2.5.1	If you process store or process data outside of the UK, please name the country and set out how the arrangements are compliant with current legislation	Not applicable	

### C3 - Technical Security

Code	Question	Answer
C3.1	Please attach your Cyber Essentials Certificate	Provided
C3.2	Please provide the summary report of an external penetration test of the product that included Open Web Application Security Project (OWASP) Top 10 vulnerabilities from within the previous 12-month period.	<p>The product is tested every two years by Jumpsec, a third-party testing specialist, on behalf of NHSE</p> <p>Please note that the product is a Windows application, not a web site and does not work in a browser</p> <p>See <a href="https://www.jumpsec.com">https://www.jumpsec.com</a></p>
C3.3	Please confirm whether all custom code had a security review.	Yes - Internal code review
C3.4	Please confirm whether all privileged accounts have appropriate Multi-Factor Authentication (MFA)?	Yes
C3.5	Please confirm whether logging and reporting requirements have been clearly defined.	Yes
C3.6	Please confirm whether the product has been load-tested	This is not something that we can do. We have no administrator access (or basic user access) to any of the servers to be able to perform any kind of load-testing. It would be up to the client's server administrator(s) to do this.

## C4 - Interoperability Criteria

Code	Question	Answer
C4.1	Does your product expose any Application Programme Interfaces (API) or integration channels for other consumers?	No
C4.1.1	<p>If yes, please provide detail and evidence:</p> <ul style="list-style-type: none"> <li>● The API's (e.g., what they connect to) set out the healthcare standards of data interoperability e.g., Health Level Seven International (HL7) / Fast Healthcare Interoperability Resources (FHIR)</li> <li>● Confirm that they follow Government Digital Services Open API Best Practice</li> <li>● Confirm they are documented and freely available</li> <li>● Third parties have reasonable access to connect</li> </ul> <p>If no, please set out why your product does not have APIs.</p>	The product is a Windows application, not a web site and does not work in a browser. There is therefore no requirement or use for APIs
C4.2	Do you use NHS number to identify patient record data?	As Cyres Cinergy is a reporting tool, it uses the most appropriate ID number for the patient as designated by each Trust. The NHS number can be used to identify the patient along with the patient ID number used by a Trust in their own systems.
C4.2.1	<p>If yes, please confirm whether it uses NHS Login to establish a user's verified NHS number.</p> <p>If no, please set out the rationale, how your product established NHS number and the associated security measures in place.</p>	<p>The login is performed as follows: username and password are linked to a Yubikey specific to each user which verifies via a third party that each user is approved to access the data.</p> <p>The application is a reporting tool. The data is read from other NHS systems, so the NHS number is presumed to be already verified.</p>



		When the NHS number is used to obtain data, the date of birth is used as an additional check. The system will only show data with a matching NHS number and date of birth.
C4.3	Does your product have the capability for read/write operations with electronic health records (EHRs) using industry standards for secure interoperability (e.g. OAuth 2.0, TLS 1.2)	No, because the product does not read / write into EHRs
C4.3.1	If yes, please detail the standard	N/A
C4.3.2	If no, please state the reasons and mitigations, methodology and security measures.	N/A
C4.4	Is your product a wearable or device, or does it integrate with them?	No

## D. Key principles for success

### D1 - Usability and Accessibility

Code	Question	Answer
D1.1	<b>Understand users and their needs in context of health and social care</b>  Do you engage users in the development of the product?	Yes
D1.1.1	If yes or working towards it, how frequently do you consider user needs in your product development and what methods	We work closely with all the SQAS teams as well as the National Office and meet regularly with lead users and senior pathologists to discuss

	do you use to engage users and understand their needs?	improvements and ideas
D1.2	<p><b>Work towards solving a whole problem for users</b></p> <p>Are all key user journeys mapped to ensure that the whole user problem is solved, or it is clear to users how it fits into their pathway or journey?</p>	Yes. Cyres Cinergy provides over 250 reports containing over 100 mandatory performance measures that get submitted by all user sites to their SQAS and on to the National Office. These reports have been tested and approved by PHE and NHSE and have been used quarterly by them for over 15 years
D1.2.1	If yes or working towards it, please attach the user journeys and/or how the product fits into a user pathway or journey	See above
D1.3	<p><b>Make the service simple to use</b></p> <p>Do you undertake user acceptance testing to validate usability of the system?</p>	Yes. The systems comprise banks of reports which have been designed in conjunction with the NHSCSP who validate them prior to being released. As these reports are largely mandatory it is essential that the algorithms that build them are approved by the national body
D1.3.1	If yes or working towards it, please attach information that demonstrates that user acceptance testing is in place to validate usability.	Please refer to the NHSCSP for confirmation
D1.4	<p><b>Make sure everyone can use the service</b></p> <p>Are you international Web Content Accessibility Guidelines (WCAG) 2.1 level AA compliant?</p>	N/A. This is a Windows based system and not designed for the web
D1.4.1	Provide a link to your published accessibility statement.	N/A
D1.5	<p><b>Create a team that includes multi-disciplinary skills and perspectives</b></p>	Yes


	Does your team contain multidisciplinary skills?	
D1.6	<b>Use agile ways of working</b> Do you use agile ways of working to deliver your product?	Yes
D1.7	<b>Iterate and improve frequently</b> Do you continuously develop your product?	Yes
D1.8	<b>Define what success looks like and be open about how your service is performing</b> Do you have a benefits case that includes your objectives and the benefits you will be measuring and have metrics that you are tracking?	Success for us is defined by the number of participating sites that use our products and whether they continue to do so. We are pleased to report that we have around 85% of the Cytology Labs and Colposcopy Clinics signed up and they renew their contracts year after year.
D1.9	<b>Choose the right tools and technology</b> Does this product meet with NHS Cloud First Strategy?	N/A. These are Windows based systems
D1.9.1	Does this product meet the NHS Internet First Policy?	N/A. These are Windows based systems
D1.10	<b>Use and contribute to open standards, common components and patterns</b> Are common components and patterns in use?	No. The product is commercial software
D1.10.1	If yes, which common components and patterns have been used?	N/A

D1.11	<p><b>Operate a reliable service</b></p> <p>Do you provide a Service Level Agreement to all customers purchasing the product?</p>	Yes – contained in our standard support agreement – available on our website
D1.12	Do you report to customers on your performance with respect to support, system performance (response times) and availability (uptime) at a frequency required by your customers?	No – not required by customers
D1.12.1	Please attach a copy of the information provided to customers	Not applicable
D1.12.2	Please provide your average service availability for the past 12 months, as a percentage to two decimal places	100%

## Supporting documentation

Question Number	Document Attached
C1.1	Cyres Ltd ICO registration certificate
C2.1	Cyres Ltd company statement on DCB0129
C2.2.1	Cyres Ltd completed ICO DPO self-assessment outcome
C2.3	Cyres Ltd company statement on GDPR
C3.1	Cyres Ltd Cyber Essentials Certificate
D1.11	Cyres Ltd standard support agreement terms – <a href="http://www.cyrescinergy.co.uk/pdf/cyres_supportterms.pdf">www.cyrescinergy.co.uk/pdf/cyres_supportterms.pdf</a>

# Do I need a Data Protection Officer (DPO)?

[Start again](#) 

1. Are you a public authority or body?

**No**

[Change this answer](#)

2. Do your organisation's core activities require regular and systematic monitoring of individuals on a large scale?

**No**

[Change this answer](#)

3. Do your organisation's core activities involve processing on a large scale 'special categories' of personal data, or 'criminal convictions or offences data'?

**No**

[Change this answer](#)

**Your organisation does not need a data protection officer.**

However, you can voluntarily appoint a DPO. It's important to note, if you do appoint one voluntarily you need to [register them with us](#).

Although you may not need to appoint a DPO, it's important to have someone in your organisation who is responsible for data protection.

Read our [guidance on data protection officers](#).

## General Data Protection Regulation – Cyres Cinergy

In response to the General Data Protection Regulation (GDPR) introduced in May 2018, Cyres have taken expert advice on the software and operations we conduct. We have since undertaken a full review and would advise current and prospective customers and partners that for the purposes of all applicable data protection and privacy legislation in force from time to time in the UK, including the General Data Protection Regulation ((EU) 2016/679) (“GDPR”) and the Data Protection Act 2018, (the “Data Protection Legislation”):

- Cyres is neither a “data controller” nor a “data processor” in relation to Cyres Cinergy software for reasons set out below. This document is intended to assist your organisation in fulfilling the regulatory requirements of the GDPR
- When referring to “data controller”, “data processor”, “processing” and “personal data”, we are using the definitions of those terms which apply under the GDPR
- Cyres has been a Microsoft Accredited Partner for over 20 years and builds all systems in line with the latest industry standards particularly as far as security and confidentiality of data is concerned
- Cyres Cinergy (including Cinergy Cytology, Cinergy Colposcopy and Cinergy Online) systems collect cervical screening data from existing Cytology Laboratory and Colposcopy Clinic systems for reporting purposes as required by the National Health Service Cervical Screening Programme (NHSCSP)
- Cyres Cinergy systems are not designed for data entry
- Cyres Cinergy systems have been designed to meet the defined standards of the NHSCSP and any upgrades are sanctioned and approved by Public Health England (PHE) before release. Such upgrades are supplied to customers for them to install and run
- Cyres has neither control nor possession over the data and we do not decide the purpose for which, nor the way in which, the data is processed
- The actual operation of the software is undertaken entirely by customers’ own staff and Cyres has no direct independent access to the software once it is operational



- At no stage does Cyres have access to any “personal data” – either identifiable or pseudonymised
- Cyres does not engage in processing since it does not obtain, record, store, update or share personal data using this system
- Cyres is therefore neither a data controller nor a data processor with regards to Cyres Cinergy systems. There is therefore no need to enter into any additional agreements
- Cyres Cinergy is standardised reporting and querying software which is used at numerous NHS sites. This enables NHS Trusts to interrogate, and to report on, data to which they have access. When we supply our software it does not store or contain any personal data
- Our software is installed on customers’ own systems rather than on an external platform managed by Cyres. During installation, Cyres does not have access to any identifiable data
- Authorised users are able to access the installed software via a UserName and Password login. These names and passwords are managed by the local administrator and allow access on a tiered basis. This means that basic users only have access to their own performance metrics whereas senior staff (consultants and administrators) have access to all metrics
- Cyres supplies an empty Microsoft SQL Server Database for the storage of data. The configuration and security of this database is the responsibility of the local IT team and should be carried out in line with local policy
- There is still the odd NHS Trust which does not use Microsoft SQL Server as the backend but opts for Microsoft Access instead. This is against Cyres recommendations. In such instances it is again the responsibility of the local IT team to load the MS Access database in a folder with appropriate permissions to ensure that security is in line with local policy
- Our software, once installed, is able to connect to the customer’s own data sources within their own systems. Any data transfer is manual and initiated by the customer
- Some NHS Trusts have access to Cyres Cinergy Online. Cyres Cinergy Online is hosted on an N3 server by Public Health England and not by ourselves. Cyres supplies initial login credentials to activate the product but has no control over the second stage of authentication, which is via a



unique Yubikey. Cyres itself does not have this two-stage access and cannot bypass it independently

- Data transfer from a local Cinergy system to the PHE National Cinergy Server meets the highest possible standards of security in that (a) it uses the HTTPS 256 bit protocol (b) Cinergy also encrypts the data to 256 bit (so there is double encryption) and (c) the data remains on the N3 network so is only accessible to authorised N3 users, and in this case only those with a registered Yubikey
- In developing this software we have considered privacy at the initial design stages and throughout the development process and we believe that Cyres Cinergy systems accord with the principles of “Privacy by Design”
- Data within Cyres Cinergy systems is held for current and historical reporting purposes. Data cannot therefore be deleted as retention could be critical in the event of the need to investigate an incident. Deletion of data would occur if the patient record was deleted in the host system i.e. the Trust system from which the data has been imported.
- There are Search facilities within Cyres systems based around key identifiers e.g. Patient Name; Patient ID; NHS No etc. Such searches will return all relevant data.
- Data can be exported in a number of ways – it can be printed or sent electronically to PDF or Excel format
- All Cyres systems are designed with full relational databases for storage meaning that each patient is stored as a single record with all associated data stored in a series of linked tables
- Cyres staff conduct staff training on a dummy system which only has access to fictitious or anonymised data which cannot be linked back to any identifiable individuals. (It is therefore not “personal data” for the purposes of the legislation)
- When providing product support, Cyres staff do not have independent access to client systems and provide only advice and guidance on the use and functionality of the software. Cyres staff will never operate software on behalf of customers
- All Cyres staff are made fully aware of the need to respect customer data security obligations when visiting customer sites. In particular, our staff are aware that no personal data should







ever be disclosed to them by our customers. If they become aware that any such disclose has occurred then they are required to report that fact so that Cyres can formally notify the customer concerned. To date, no such disclosures have occurred

September 2020





# CERTIFICATE OF ASSURANCE

Cyres Ltd

Eldo House Suffolk Business Park Bury St Edmunds IP32 7AR

**COMPLIES WITH THE REQUIREMENTS OF THE CYBER ESSENTIALS SCHEME**

NAME OF ASSESSOR : Prakash Joshi

CERTIFICATE NUMBER : 7a8486e8-f8dd-4753-ab50-9617a7a8a336

DATE OF CERTIFICATION : 2024-03-12

PROFILE VERSION : 3.1 (Montpellier)

RECERTIFICATION DUE : 2025-03-12

SCOPE : Whole Organisation



**SCAN QR CODE TO VERIFY THE AUTHENTICITY OF THIS CERTIFICATE**

CERTIFICATION MARK



CERTIFICATION BODY



CYBER ESSENTIALS PARTNER



The Certificate certifies that the organisation was assessed as meeting the Cyber Essentials implementation profile and thus that, at the time of testing, the organisations ICT defences were assessed as satisfactory against commodity based cyber attack. However, this Certificate does not in any way guarantee that the organisations defences will remain satisfactory against a cyber attack.

# Software Maintenance Terms

## PARTIES:

- (1) **“Cyres”**: CYRES LIMITED whose registered office is at Knights Lowe, Eldo House, Kempson Way, Bury St Edmunds IP32 7AR and
- (2) **“The Client”**: The party with whom Cyres has entered into the agreement to which these terms apply.

These terms (“the Terms”) set out the basis on which Cyres agrees to provide software maintenance services to the Client in respect of the software defined below.

## 1 DEFINITIONS

“the Agreement”	means the contract between Cyres and the Client comprising the Proposal and these Terms.
“the Contact Person”	means the person specified as such in the Proposal. If no such person is specified then the person to whom the Proposal is addressed, or where the Proposal is not addressed to an individual, the person who authorised the installation of the Software.
“Designated Contact Details”	means (a) telephone number 01223 655674 (b) email address <a href="mailto:support@cyres.co.uk">support@cyres.co.uk</a> or any other details notified by Cyres at any time for the purpose of notifying Support Issues.
“the Documentation”	means the user-manuals and other explanatory materials relating to the Software or any Version Upgrade (whether in printed or electronic format) provided by Cyres to assist the Client in making use of the Software.
“Initial Term”	means the period set out in the Proposal commencing with the Start Date. Where no such period is stated then it means 12 calendar months.
“the Location”	means the address at which the Software is installed as stated in the Proposal. If no such address is specified, then the address of the Client at which the Software was originally installed by Cyres.
“Prevailing Rates”	means Cyres standard prices and payment terms, as revised from time to time, details of which are available at any time upon written request.
“the Proposal”	means the written proposal or the written offer of services or the written description of services by Cyres (as referred to in clause 2.1 ) which is expressed to incorporate these Terms.
“Renewal Date”	means the day following the end of the Initial Term and, thereafter, the day following the end of each subsequent Renewal Period
“Renewal Period”	means the period commencing on a Renewal Date and lasting for a period equal to the duration of the Initial Term.
“the Start Date”	means the date of the beginning of the period of software support as stated in the Proposal. Where no such date is specified it means the date on which the Software is installed at the Location by Cyres.
“the Software”	means the computer program described or referred to in the Proposal (but not the media on which it is stored).



“Support Issue”	means any error or defect in the Software at the Location which causes it not to perform in accordance with the functionality set out in the Documentation.
“Version Upgrades”	means updated versions of the Software issued from time to time to the Client, at Cyres’ discretion, to improve the functionality of the Software.
“Working Day”	means any day Monday to Friday 9:00 am to 5:00 pm excluding weekends and UK bank, national and public holidays.

## 2 FORMATION OF CONTRACT

- 2.1 The Terms form part of any contract made between Cyres and the Client by means of:
  - 2.1.1 The Client accepting a written proposal from Cyres which is expressed to incorporate these Terms or
  - 2.1.2 The Client placing an order for software maintenance, the provision of which has been expressed by Cyres (on its website, by email, letter, previous invoice or otherwise) to be subject to these Terms or
  - 2.1.3 The Client paying an invoice for renewal or extension of any existing software maintenance contract between Cyres and the Client where such invoice expressly incorporates Cyres’ terms of business.
- 2.2 In the case of any conflict between these Terms and the Proposal the Proposal shall prevail.
- 2.3 These Terms shall apply to the Agreement to the exclusion of any other terms and conditions contained in a Client purchase order or which the Client may otherwise purport to incorporate. Notwithstanding any statement to the contrary, the receipt of a formal Client purchase order by Cyres shall be deemed to constitute acceptance by the Client of an offer of services by Cyres, subject only to these Terms.
- 2.4 The Agreement shall supersede all prior arrangements between the parties in respect of the Software and the Documentation.
- 2.5 The Agreement will represent the whole of the agreement reached between the parties and the Client acknowledges that in entering into the Agreement it is not relying on any previous statement made by or on behalf of Cyres.
- 2.6 No variation of the Agreement shall be binding unless agreed in writing between a director of Cyres and a duly authorised representative of the Client.

## 3 DURATION OF AGREEMENT

- 3.1 This Agreement shall commence on the Start Date and be for an initial period of the Initial Term and thereafter it shall be automatically renewed on each subsequent Renewal Date for each subsequent Renewal Period unless terminated as provided in the Agreement.

## 4 MAINTENANCE SERVICE

- 4.1 Cyres agrees to provide the following services for the duration of the Agreement in respect of the Software installed at the Location during normal Working Days:
  - 4.1.1 Cyres will provide access to suitably skilled support staff via telephone, email or post to assist the Client to resolve Support Issues.
  - 4.1.2 Support Issues may only be notified by the Contact Person using the Designated Contact Details during Working Days.
  - 4.1.3 Where notification is by telephone, Cyres reserves the right to require that the notification be confirmed in detail in writing.
  - 4.1.4 Cyres will respond within four (4) hours of receipt of notification and will give the Contact Person an initial indication of how the matter will be dealt with. Thereafter, Cyres will, as soon as reasonably practicable, assign a priority status to the Support Issue and inform the Contact Person accordingly.
  - 4.1.5 If the Support Issue is such that the Client’s staff are completely unable to perform the duties they would normally undertake using the Software then Cyres will assign it the highest priority and will undertake the resolution of the Support Issue prior to any other support activities and as soon as appropriate resources are available.



- 4.1.6 If the Support Issue is apparent but is not such that the Client's staff are completely unable to perform the duties they would normally undertake using the Software then Cyres will undertake the resolution of the Support Issue as soon as reasonably practicable.
- 4.1.7 If the Support Issue is minor or trivial then Cyres will undertake its resolution at a mutually convenient time.
- 4.1.8 If the Support Issue cannot be resolved by remote computer access or, with the assistance of the Client's staff, by telephone or email, then Cyres will arrange for a member of its technical support staff to visit the Location to resolve it. The scheduling of the visit will reflect the priority assigned by Cyres to the Support Issue.
- 4.1.9 The priority status assigned to any Support Issue shall be at the sole discretion of Cyres' authorised technical staff.
- 4.2 Cyres will ensure that its support staff comply in all appropriate and relevant respects with Cyres' own standard "Code of Conduct for the Delivery of Professional Services" (available at [www.cyrescinergy.co.uk](http://www.cyrescinergy.co.uk))
- 4.3 The Client agrees:
  - 4.3.1 To provide whatever information, reports and data Cyres may reasonably require to enable the Support Issue to be investigated and resolved effectively.
  - 4.3.2 To carry out all reasonable instructions of Cyres' support staff in order to assist with the resolution of any Support Issue by the installation, testing and utilisation of software and otherwise.
  - 4.3.3 To ensure that the Contact Person, and any deputy performing that role, have received appropriate training in the operation of the Software.
  - 4.3.4 To install any revision of the Software (in accordance with Cyres' instructions) to correct the Support Issue within 30 days of receipt by the Client. If the Client is unable or unwilling to install the revision then it must notify Cyres accordingly in writing within ten (10) days of receipt and thereafter allow Cyres to make arrangements to install the revision at the Location. Such installation by Cyres shall be chargeable to the Client (in respect of time, travel, accommodation and subsistence) at Cyres' Prevailing Rates.
  - 4.3.5 To ensure that suitable backup software, equipment and procedures are in operation at all times to ensure that there is no risk of irretrievable data loss from the Client's systems on which the Software is installed.
- 4.4 Where a member of Cyres' technical staff ("the Representative") visits the Location to undertake the resolution of a Support Issue, the Client will ensure that:
  - 4.4.1 A member of staff is available to meet the Representative on arrival and to arrange parking (if necessary) at the Location.
  - 4.4.2 Within thirty (30) minutes of the Representative's arrival at the Location, the Representative is given such access to the Software on the Computers (and any other software and computers) as the Representative reasonably requires.
  - 4.4.3 The Representative is advised as to the means of escape in the event of fire and any other appropriate health and safety instructions.
  - 4.4.4 All necessary and reasonable steps are taken to ensure the personal safety of the Representative and the safety and security of the Representative's personal and business property.
  - 4.4.5 All assistance, software, computer equipment, presentation equipment and other facilities reasonably requested by the Representative shall be provided promptly and without cost.
- 4.5 Cyres reserves the right to insist that all revisions (as described in clause 4.3.3) and all Version Upgrades already issued to the Client are installed prior to Cyres responding to any new Support Issue.
- 4.6 The Contact Person may at any time nominate a deputy to act in their absence to perform the duties of the Contact Person for such period as they may notify. Such deputy must have received appropriate prior training in the operation of the Software. During that period the deputy shall be deemed to be the Contact Person and the original Contact Person shall not be treated as the Contact Person.
- 4.7 For the avoidance of doubt, no computer software other than the Software and no Software at any address other than the Location will be covered by this Agreement. Any additional computer software to be covered and any alternative



addresses can only be included in the Agreement by express written agreement by Cyres to include them within the scope of the Software and the Location as defined above.

- 4.8 The Agreement does not cover any Support Issue arising from or in connection with:
- 4.8.1 Any computer virus on the Client's computer systems.
  - 4.8.2 Installation of the Software on any computer or computer system unless carried out by, or at the direction of, Cyres.
  - 4.8.3 Any modification or alteration of the Software other than by, or at the direction of, Cyres.
  - 4.8.4 Operation of the Software on any computer operating system not previously approved by Cyres.
  - 4.8.5 Any failure or defect in the Client's internet, telecommunications or remote access systems.
  - 4.8.6 The alteration by the Client of any network settings, system settings or security permissions in relation to the Computers or the Location.
- 4.9 Where any support requirements notified to Cyres are investigated and subsequently identified by Cyres as not being covered by this Agreement then the Client shall be liable to pay for Cyres' time and expense incurred in investigating the issue at Cyres' Prevailing Rates.
- 4.10 The Client shall be liable to pay Cyres' additional charges in accordance with the Prevailing Rates in respect of any time costs, expenses or other work incurred by Cyres by reason of any breach of the Client's obligations set out in clause 4.3.

## 5 VERSION UPGRADES

- 5.1 Cyres agrees to supply the Client with:
- 5.1.1 The latest version of the Software as formally released from time to time as a Version Upgrade.
  - 5.1.2 One copy of the Documentation relevant to the Version Upgrade in electronic format.
- 5.2 Version Upgrades of the Software will be supplied on suitable media. Cyres reserves the right to charge for such media and relevant carriage charges at cost.
- 5.3 The Client agrees to install each Version Upgrade (in accordance with Cyres' instructions) within 30 days of receipt by the Client. If the Client is unable or unwilling to install a Version Upgrade then it must notify Cyres accordingly in writing within ten (10) days of receipt and thereafter allow Cyres to make arrangements to install the Version Upgrade at the Location. Such installation by Cyres shall be chargeable to the Client (in respect of time, travel, accommodation and subsistence) at Cyres' Prevailing Rates.
- 5.4 In respect of any Version Upgrade issued, the terms under the headings "Grant of Licence" and "Intellectual Property Rights" set out in Cyres' standard "Non-Exclusive End-User Licence Terms" (available at [www.cyrescinergy.co.uk](http://www.cyrescinergy.co.uk)) shall apply *mutatis mutandis* in respect of such Version Upgrades and related Documentation as if those terms were incorporated herein and as if the Version Upgrade and related Documentation were the "Software" and "Documentation" referred to in those terms.

## 6 PAYMENT

- 6.1 In consideration of the services provided under the Agreement the Client agrees to pay (together with any applicable VAT):
- 6.1.1 In respect of the Initial Term, the price stated in the Proposal.
  - 6.1.2 In respect of any Renewal Period, the Cyres' support charge in accordance with the Prevailing Rates applicable to the Software as at the applicable Renewal Date.
- 6.2 Payment terms shall be as set out in the Proposal. If no payment terms are stated then payment is due within 14 days of the date of Cyres' invoice.
- 6.3 The Client shall pay all sums due under the Agreement in full without any discount, deduction, set-off or abatement on any grounds.
- 6.4 If any sum payable under the Agreement remains unpaid 30 days after falling due then (without prejudice to any other rights or remedies Cyres may have) Cyres may:



6.4.1 Charge the Client interest on the sum outstanding on a daily basis (both before any after judgement) from the due date until the date paid at the rate of 5% p.a. above the Royal Bank of Scotland base rate in force from time to time and

6.4.2 Suspend performance of all or any of its outstanding obligations under the Agreement until full payment is made.

6.5 If, as a result of anything the Client does or fails to do (which is not covered by clause 11) Cyres is prevented from or delayed in performing any of its obligations under the Agreement then the Client shall be liable to pay Cyres for any reasonable time costs, expenses or losses that Cyres has incurred as a result in accordance with the Prevailing Rates.

## 7 INTELLECTUAL PROPERTY RIGHTS

7.1 The Client agrees that no copyright, design right or any other kind of intellectual property right in the Software or the Documentation shall pass to the Client by virtue of the Agreement.

## 8 WARRANTIES AND LIABILITY

8.1 Except in respect of death or personal injury caused by the negligence of Cyres, its employees or agents (and otherwise to the fullest extent permitted by law), Cyres expressly excludes liability for breach of any terms, conditions or warranties implied by law.

8.2 No express warranties are made as to the fitness or suitability of the Software or Version Upgrades for any particular purpose or otherwise.

8.3 Notwithstanding any other term of the Agreement, Cyres shall not be liable to the Client for any loss of profits, loss of contracts, loss of or corruption of computer data or any other indirect or consequential loss howsoever arising.

8.4 Without prejudice to the foregoing provisions of clause 8, the total amount of any liability of Cyres arising in connection with the Agreement shall not exceed the amount of the price paid by the Client in respect of the Initial Term.

## 9 TERMINATION

9.1 Either party may terminate the Agreement at any time after the Initial Term on giving not less than three (3) calendar months notice to expire on or at any time after the end of the Initial Term.

9.2 Cyres may terminate the Agreement (without prejudice to any other rights or remedies Cyres may have) at any time if:

9.2.1 Any sum payable under the Agreement remains unpaid 60 days after falling due or

9.2.2 The Client has been in material breach of any other obligation under the Agreement for a period of 21 days after Cyres has given it notice of such breach

9.2.3 The Client fails to provide an official purchase order, against which Cyres can raise a VAT invoice for any sum payable under the Agreement, 21 days after Cyres has requested such order

9.3 Either party may terminate the Agreement if the other convenes a meeting of its creditors or if a proposal is made for a voluntary arrangement under the Insolvency Act 1986 or a proposal or any other composition scheme or arrangement with (or assignment for the benefit of) its creditors or if the other shall be unable to pay its debts within the meaning of s123 of the Insolvency Act 1986 or if a trustee receiver administrative receiver or similar officer is appointed in respect of all or any part of the business or assets of the other or if a petition is presented or a meeting is convened for the purpose of considering a resolution or other steps are taken for the winding up of the other or for the making of an administration order (other than for the purpose of an amalgamation or reconstruction).

9.4 Upon termination of the Agreement the Client will remove the Software and any Version Upgrades from its computer systems and will return all copies of the Software, Version Upgrades and the Documentation to Cyres within 30 days or otherwise destroy or dispose of them as Cyres may direct.

9.5 Termination of the Agreement shall be without prejudice to any accrued rights or liabilities nor the continuation in force of any provision which is expressly or by implication intended to continue in force after such termination.

## 10 CONFIDENTIALITY

10.1 Both parties shall treat as confidential all information obtained from the other pursuant to the Agreement and neither shall divulge such information to any person (except to their own respective employees and then only to those employees who need to know the same) without the other's prior written consent. This obligation shall not extend to information which was rightfully in the possession of either party before the commencement of the negotiations leading





to the Agreement, or which was already public knowledge or which becomes so at a future date (otherwise than as a result of a breach of this obligation) or which is trivial or obvious.

- 10.2 Both parties shall ensure that their employees are aware of and comply with the provisions of clause 10.1. If either party appoints any sub-contractor it may disclose confidential information to such sub-contractor subject to such sub-contractor giving a similar undertaking to that contained here. These obligations as to confidentiality shall survive any termination of the Agreement.

## **11 FORCE MAJEURE**

- 11.1 Notwithstanding anything else contained in the Agreement if either party is forced to delay the performance of any obligation under the Agreement by reason of acts of God, strikes, civil commotion, war, fire, explosion, sabotage, flood, earthquake, breakdown in public telecommunications networks or any other circumstances beyond the reasonable control of the party concerned then, provided that the delaying party promptly notifies the other of the reasons for the delay (and its likely duration), the performance of that party's obligations shall be suspended whilst the said circumstances persist unless they were caused by the act or omission of the party concerned (in which event the other's rights and remedies shall be those conferred and imposed by the other terms of the Agreement and by law).

- 11.2 Either party may, if the said circumstances persist for more than thirty (30) days terminate the Agreement on giving the other seven (7) days notice. If the Agreement is so terminated neither party shall as a result be liable to the other except that the Client shall pay Cyres a reasonable sum in respect of any work Cyres has carried out before termination. Cyres shall be entitled to deduct such sum from any amounts the Client has previously paid under the Agreement and will at Cyres' discretion return the balance (if any) to the Client.

## **12 WAIVER OF REMEDIES**

- 12.1 No forbearance delay or indulgence by either party in enforcing the provisions of the Agreement shall prejudice or restrict their respective rights. No waiver of either's rights will operate as a waiver of any subsequent breach. No right power or remedy herein conferred upon or reserved to either party is exclusive of any other available right power or remedy and such rights powers or remedies shall be cumulative.

## **13 ASSIGNMENT**

- 13.1 The Client may not assign or otherwise transfer, in whole or in part, any or all of its rights and/or obligations under the Agreement without the prior written consent of Cyres.

## **14 NOTICES**

- 14.1 With the exception of notification of Support Issues, any notice required to be given shall be in writing and shall be sent to the last known address of the recipient or such other address as the recipient may designate by notice given in accordance with the provisions of this clause. Any such notice may be delivered personally, or by first class pre-paid letter, email or fax transmission and shall be deemed to have been served if by hand when delivered, if by first class post 48 hours after posting, and if by email or fax when dispatched (provided that a confirming copy is sent by post in accordance with this clause).

## **15 LAW**

- 15.1 The Agreement shall be governed by and construed in accordance with English law and the parties agree to submit to the exclusive jurisdiction of the English courts.





# Data Protection Registration Certificate

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## CYRES LIMITED

c/o Knights Lowe  
Eldo House  
Kempson Way  
Bury St Edmunds  
Suffolk, IP32 7AR

Registration reference: Z8607789

Date registered: 17 May 2004

Registration expires: 16 May 2025



Issued by: Information Commissioner's Office,  
Wycliffe House, Water Lane, Wilmslow, Cheshire  
SK9 5AF

Telephone: 0303 123 1113

Website: [ico.org.uk](https://ico.org.uk)



# 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 <i>Clinical Risk Management: its Application in the Manufacture of Health IT Systems</i> 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 - <a href="https://digital.nhs.uk/services/clinical-safety/applicability-of-dcb-0129-and-dcb-0160">https://digital.nhs.uk/services/clinical-safety/applicability-of-dcb-0129-and-dcb-0160</a> - 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 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”.



### **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”.



- 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.

December 2022

