assuring healthcare technology

G-Cloud 15

Service Definition

Digital health regulatory and compliance consultancy for DCB0129 and DCB0160

Safehand Consulting Limited

Lot 3 Cloud Support Services (Additional Services)

1. Introduction

Company Overview

Safehand is the UK's leading provider of outsourced Clinical Safety Officer services. We deliver specialist consultancy and training to support organisations in managing their digital health compliance obligations. Our expertise helps customers achieve rapid compliance with mandatory standards such as DCB 0129, DCB 0160 and the Medical Device Regulations, while also enhancing quality, securing clinician engagement and improving patient safety.

Since our establishment in March 2016, we have grown rapidly and now manage the regulatory interests of more than 150 software suppliers and healthcare organisations worldwide. Our customers range from small start-ups to some of the largest global health IT companies. We also work extensively with UK NHS Trusts and Integrated Care Boards (ICBs), guiding them through the complexities of the regulatory landscape

We currently employ sixteen full time Clinical Safety Officers. Our goal is to make the lives of our customers simpler through clear explanation, precision and clarity of thought. We thrive on being straight-forward, plain-speaking and easy to do business with.

Value Proposition

DCB 0129 and DCB 0160 are mandatory UK risk management standards and a core part of the Digital Technology Assessment Criteria (DTAC). Any healthcare organisation developing or implementing health IT systems must comply, and the work must be carried out by a registered clinician. The work culminates in the issuing of a series of compliance documents. For those undertaking this alongside their clinical duties, the process can be resource-intensive, time-consuming and frustrating,

Safehand makes this easier. We provide expert consultancy to help healthcare organisations meet their obligations efficiently and with confidence. We can either supply experienced Clinical Safety Officers to deliver the required documentation on your behalf, or support you in building in-house capability to manage DCB 0129 and DCB 0160 compliance independently.

What the Service Provides

Safehand can provide services to:

- Deliver the full suite of DCB 0129 and DCB 0160 documentation on behalf of healthcare organisations, saving the time and cost of appointing, training and allocating local staff
- Act as the Clinical Safety Officer for a product or implementation project, avoiding the need to divert valuable local clinical resources
- Review, audit and provide oversight of DCB 0129/0160 work already completed by healthcare organisations

- Support healthcare organisations in developing their own sustainable Clinical Risk Management capability
- Assess and report on assurance debt in systems that have not previously been reviewed under DCB 0160
- Provide tailored on-site training courses covering DCB 0129 and DCB 0160

Social Value

Mission: Kick start economic growth. Policy Outcome 1: Fair work.

1b – Fair working conditions: Employment contracts that reflect actual hours worked; steps taken to ensure employees understand their contracts and have the ability to review and adjust them if actual hours regularly exceed contracted hours.

Approach

We are committed to ensuring that all staff have employment contracts that reflect their actual working hours and that they fully understand their contractual terms. As timesheet data sits with senior management, they will conduct a transparent review of contracted hours and hours paid against hours worked. Our approach is proportionate, transparent and time-bound.

Method Statement

Contract and Hours Review

- Within the first 30 days, the Managing Partner and COO will conduct a full review of each employee's contracted hours versus actual hours worked (based on the previous 12 weeks of timesheets).
- Staff whose actual hours exceed contracted hours by 10% or more will be identified for review.
- A summary baseline report will be completed within one month.

Alignment of Contracts to Actual Hours

- The Managing Partner or COO will hold individual discussions with affected staff within 8 weeks to agree contract amendments or adjustments to workload.
- 95% of any required contract amendments will be completed within 12 weeks.

Ongoing Monitoring

- The Managing Partner and COO will review timesheet data quarterly to identify any employee whose hours exceed contracted levels by 10% or more.
- Any flagged discrepancy will trigger a mandatory follow-up discussion within 10 working days, recorded in an internal log.
- Actions may include contract amendments or workload adjustment.

Governance

- The Managing Partner is accountable for oversight and reporting.
- Quarterly leadership reviews will track progress against KPIs, staff feedback and process improvements.
- An annual review will ensure contracts remain aligned to working patterns.

KPIs

- 100% of staff receive a contract and hours review within 30 days.
- 95% of contract amendments completed within 12 weeks.
- 100% of discrepancies reviewed within 10 working days.
- Documented quarterly monitoring and quarterly governance reports.

1c – Fair pay practices: Payment of more than the National Minimum Wage or National Living Wage (as appropriate) to the contract workforce.

Commitment:
All staff engaged in this contract are paid above the National Living Wage, in line with Social Value Model PPN002.

Method Statement and Project Plan:
The Managing Partner oversees all timesheets and payroll to ensure compliance. Payslips clearly show hourly rates, hours worked, and total pay. Monthly reviews of payroll against hours worked confirm that all staff receive above National Living Wage. Any discrepancy is corrected immediately.

Updates to the National Living Wage are incorporated promptly, ensuring ongoing compliance. Quarterly internal audits of payroll and timesheets document adherence, and any anomalies are resolved. Annually, pay rates are benchmarked against the latest statutory figures to maintain above-minimum standards.

Measurable Outcomes:

- 100% of staff paid above the National Living Wage.
- Monthly payroll verification completed and documented.
- Quarterly audits and annual pay benchmarking ensure sustained compliance.

This approach provides a transparent, measurable, and time-bound framework for delivering fair pay practices for all staff under this contract.

1c – Fair pay practices: Monitoring and reporting of gender and ethnicity pay gaps and plans to address them where necessary.

Commitment:
We will monitor and report on gender and ethnicity pay gaps for all staff engaged in this

contract and take corrective action where necessary, in line with Social Value Model PPN002.

Method Statement and Project Plan:
We are committed to maintaining fair and equitable pay across our workforce. Although our organisation (16 employees) is not legally required to publish pay gap data, we will voluntarily monitor and review gender and ethnicity pay equity as part of our commitment to fair work and responsible employment. Pay decisions will continue to be based solely on objective criteria such as skills, responsibilities, qualifications and demonstrable performance.

The Managing Partner and COO will jointly oversee pay gap monitoring, review results and ensure corrective action is taken where it cannot be objectively justified.

A baseline assessment of gender and ethnicity pay data, including salary and benefits, will be completed within three months of contract award, with findings documented and shared internally. Results will be reviewed annually in Q4, comparing year-on-year trends and identifying any unjustified pay gaps.

Where a pay gap above 5% is identified without objective justification, a corrective action plan will be implemented within three months, which may include pay adjustments, role evaluation or progression support.

Measurable Outcomes:

- Baseline gender and ethnicity pay gap assessment completed within three months.
- Annual Q4 analysis and reporting to staff.
- Corrective action plans implemented for any gap >5% within three months.

1d – In-work progression to help people move into higher paid work by developing new skills: Support for the contract workforce by providing career advice, and providing opportunities for staff working on the contract with in-work progression career development into known skills shortages or high growth areas. Illustrative examples: mentoring; mock interviews; CV advice and careers guidance; learning and development; volunteering; careers talks, curriculum support, literacy support and safety talks.

Method Statement

Safehand Consulting is a specialist digital clinical safety consultancy, providing expertise to NHS organisations and suppliers in compliance with DCB 0129/0160 and wider risk management frameworks.

Our workforce comprises highly skilled professionals who are supported through a continuously evolving professional development framework. We are committed to **Outcome 1d** of the Social Value Model – enabling in-work progression into higher-paid roles by equipping people with new skills, confidence, and real-world experience through our

internal Clinical Safety Progression Pathway (CSPP). This provides structured learning and mentoring enabling Clinical Safety Officers (CSOs) to move into more senior, higher-paid, and more impactful roles.

Commitments

Our specific, measurable and time-bound commitments are:

- Support at least 20% of our CSOs to move into higher-paid roles within 24 months.
- Provide access to structured and accredited training, including a two-day CSO training course delivered in partnership with NHS organisations.
- Deliver a minimum of 24 CPD sessions per year, led by senior CSOs, covering advanced and emerging risk management topics.
- Offer intensive support for all new starters over their first 6 months, including on-the-job coaching, topic-focused training, and weekly mentoring sessions.
- Ensure 100% of staff receive structured reviews at 3 and 6 months, and annual appraisals thereafter, that includes career development discussion.
- Enable professional progression through specialist career routes, allowing staff growth and remuneration based on knowledge and expertise.

Training and Development Approach

Structured CPD Programme
We host fortnightly CPD sessions led by senior CSOs, covering topics such as digital safety case development, AI in health IT, medical device regulation, and emerging trends in digital clinical safety and regulatory policy. These are complemented by insights from staff attending conferences, industry events, and webinars.

These sessions are designed not only to upskill staff but to cultivate leadership, critical thinking, and strategic understanding. We operate a monthly attendance rota for a national CSO Community event to ensure all CSOs gain exposure and actively contribute to the wider CSO community.

Accredited Training
All staff are offered attendance at a two-day CSO training course, delivered in-person to NHS clients, allowing further development of their subject matter expertise in a real-world setting.

Mentoring and Coaching
Every new starter receives a two-day induction followed by a six-month structured support programme. All our CSOs have weekly one-hour sessions with their line manager and mentor and extended coaching embedded within live consultancy work. They can also contact other team members with specific knowledge in specialist areas as required.

Supervised Project Work

Staff are closely supervised during live consultancy work with NHS and supplier clients. They receive timely, constructive feedback and gain practical experience in areas such as safety case authorship, hazard identification, control verification, and regulatory communication.

Internal Knowledge Base

Our team maintains an internal wiki of guidance, procedures, and learning materials, which is regularly updated with insights from CPD sessions and customer feedback.

Career Pathway and Appraisals

All staff are supported through formal reviews at 3, 6 and 12 months, followed by annual appraisals. These reviews focus on skills development, progress against identified personal and professional development objectives and future career direction including the options of becoming a project specialist Senior CSO or Team Lead. Staff can progress into higher-paid roles without needing to manage others, recognising professional excellence in all forms.

Alignment with the Social Value Model (PPN 002) - MAC 1d - In-work progression to help people to move into higher paid work by developing new skills

- CSPP increases the number of qualified professionals capable of delivering advanced digital clinical safety services to customers.
- Part-time and flexible working supported, ensuring fair and equitable access to training, mentoring, and career progression.
- Transparent advancement and inclusive CPD access promoted, encouraging progression based on capability and commitment, not background.

Project Plan

Phase	**Activity**	**Timeline**	**Output**	**KPI**
Training Delivery	Run CPD sessions and CSO courses	Ongoing	24+ CPD sessions annually	≥90% attendance at CPD 100% access to CSO course
Coaching & Mentoring	Weekly sessions with mentors during first 6 months	Months 1–6 (new staff)	Mentorship logs	100% of new staff mentored

Review & Appraisal	Conduct 3-, 6-, and 12-month reviews	Months 3–12	Development review records	100% staff reviewed on time
Progression Monitoring	Assess readiness for higher-paid roles	Months 12 onwards	Promotions and salary reviews	≥20% staff progressed

Legacy and Sustainability

The Clinical Safety Progression Pathway is a permanent feature of Safehand's culture and business model. However, it will continue to evolve with sector needs, emerging technologies, and regulatory and policy changes. Our investment in training, structured mentoring, and non-linear progression routes ensures that every team member is supported not only to do their job, but to grow into a leader, trainer, or subject expert in digital clinical safety. Our reflective learning model—where CSOs bring insights from live delivery back into internal development—keeps our content current, and our team future-ready.

1d – In-work progression to help people move into higher paid work by developing new skills: Volunteering opportunities for staff.

Commitment

Our organisation will support in-work progression through volunteering by providing every employee with one paid volunteering day per year, which may be taken as a single full day or split into shorter sessions, to undertake voluntary work that develops transferable skills. Volunteering will build capabilities that support career advancement into higher-paid roles, such as communication, leadership, mentoring, digital literacy, and project coordination.

Method Statement

Employees are encouraged to use paid volunteering time for activities that benefit the community while enhancing relevant skills. Staff will propose preferred volunteering opportunities aligned with personal development goals and the COO approves based on fairness and relevance to skills growth.

All volunteering activity (full day or split sessions) will be recorded on a central register and monitored quarterly. After completing volunteering activities, employees will submit a brief reflection outlining the skills gained and how these contribute to their progression. Line managers will review these reflections during annual appraisals and consider relevant outcomes when discussing training, development, and career progression.

Project Plan, KPIs and Milestones

Milestone / Activity	Measure / KPI	Timeframe
Publish volunteering policy	Policy communicated to all staff	Within 1 month of contract start
Agree volunteering opportunities	% of staff with approved volunteering plan	Within 3 months
Completion of annual volunteering time	100% of staff offered one paid day; target ≥75% uptake per year	Annually
Submission of reflections	100% of participants submit reflection within 10 working days of completing volunteering	Ongoing
Review outcomes at appraisal	Line managers consider reflections when discussing training and development	Annually

Overview of the G-Cloud Service

DCB 0129/0160 drafting and Clinical Safety Officer services:

Safehand works in partnership with you to assess your system or implementation and produce the required DCB 0129/0160 documentation. This typically includes a Clinical Risk Management Plan, Hazard Log and Clinical Safety Case Report, developed through detailed consultation with your project team. We also deliver professionally facilitated Clinical Risk Management Workshops. For DCB 0160 projects, we carry out a rigorous review of the supplier's DCB 0129 materials, ensuring key hazards and controls are appropriately transferred and integrated into your local documentation.

Our team of sixteen full-time Clinical Safety Officers (CSOs) comprises doctors, nurses, pharmacists, midwives, speech and language therapists and occupational therapists. Each has extensive hands-on experience of implementing health IT systems within the NHS.

DCB 0129/0160 capability development services:

Safehand will work with you to examine your existing resources and collateral and help you to build a local Clinical Risk Management and Clinical Safety Officer function. The services will typically include:

- Training for nominated Clinical Safety Officers and supporting staff
- Stakeholder analysis to identify and train a local Safety Sponsor
- Review of existing systems to assess assurance debt and prioritise legacy remediation work
- Strategic advice on the structure and composition of a Clinical Risk Management Team
- Development of local processes and business functions
- Supervision of document drafting through structured review and feedback

A typical engagement comprises three phases:

1. **Discovery** – working with you to assess existing resources, skills, assurance debt and accountability structures
2. **Strategic Remediation** – addressing identified gaps, securing additional resources if needed, training staff and developing reusable collateral
3. **Specialist Support** – delivering targeted, customisable activities to build local capabilities tailored to your organisational needs

Onsite training courses:

Safehand delivers CPD-accredited clinical safety training directly at your site for Clinical Safety Officers and wider project teams (see pricing document). The course covers the detailed techniques of proactive clinical risk management and compliance with DCB 0129 and DCB 0160.

This two-day course equips delegates with the knowledge and practical skills to ensure patient safety is prioritised when developing or implementing health IT systems. The training focuses not only on what compliance requires, but also on how to achieve it effectively with the resources available to you.

Courses are delivered on-site over two consecutive days, allowing unlimited attendance from your organisation. This approach helps embed a culture of clinical safety across the wider team, rather than restricting it to the Clinical Safety Officer role.

Our training can serve as an alternative to the NHS England course, or as an advanced masterclass to build on existing knowledge. Content is flexible and tailored to your needs, whether that involves engaging suppliers and customers on safety, understanding the implications of the Medical Device Regulation, or clarifying the responsibilities of the Clinical Safety Officer.

Delegates can claim 11 CPD points on completion.

2. Data Protection

Information Assurance

Safehand has rigorous Information Security and Data Protection Policies in place and holds CyberEssentials Plus certification. All confidential data is stored on a Microsoft secure

platform and no data is maintained locally. Individual Clinical Safety Officers can only access data pertaining to their own projects to avoid conflicts of interest.

Data Back-Up and Restoration

Safehand's data is stored entirely in the cloud. Files are automatically backed up every two hours to a secure server and can be restored either individually or in full within one hour.

Business continuity statement/plan

Safehand's staff are geographically separated such that there is minimal opportunity for complete service discontinuity. The business's only dependency is access to our cloud-based filestore. This service is hosted by Microsoft on a highly resilient platform.

Privacy by Design

Safehand has rigorous Information Security and Data Protection Policies in place. Safehand does not store citizen's data beyond the names and addresses of our employees and subscribers to our website. All data is held on a cloud-based secure Microsoft server. The use of removable media is not permitted.

3. Using the service

Ordering and Invoicing

Our services can be ordered following a discussion with a member of our team. We will formulate a proposed strategy for the engagement incorporating our costs based on the Pricing Document and estimated effort required. The engagement can commence following the receipt of a Purchase Order.

Our services are invoiced on a time and materials basis each month, for work undertaken in the previous month.

To discuss your requirements in more detail, contact us at contactus@safehand.co.uk or telephone +44 (0)114 4000455.

Availability of Trial Service

Not applicable - Safehand provides consultancy services which cannot realistically be made available on a trial basis.

On-Boarding, Off-Boarding, Service Migration, Scope etc.

For DCB 0129 and 0160 drafting projects, Safehand employs a formal on-boarding process whereby the healthcare organisation is sent appropriate materials for them to complete in order for us to capture the information to undertake the project. The manner in which we solicit the information is designed to be as simple and straight-forward as possible to minimise effort on the healthcare organisation's part.

Where Safehand provides strategic support, we will walk our customers through a number of exercises to examine their levels of assurance debt, assess their existing documentation

and explore options for building a robust team. These activities inform the subsequent strategy to build a local Clinical Risk Management capability.

Should an organisation discontinue our services, we will provide all materials in editable format to enable them to be maintained by the healthcare organisation following our exit.

Training

For DCB 0129/0160 drafting projects, we will provide the necessary briefings to ensure that the healthcare organisation is best able to engage with the activities. This is conducted remotely and the costs of providing these briefs is included in the effort quoted for the project.

Where we provide training courses, these are typically conducted on site at our customer's premises over a two-day period.

Implementation Plan

A detailed implementation plan can be provided to the buyer on request. This will outline the key activities of each stakeholder, the end to end workflow and the deliverables which will be produced at each milestone.

Service Management

Safehand provides supporting services to act as the Clinical Safety Officer for an organisation or product on an on-going basis. The effort required to do this varies depending on the size, complexity and risk associated with the product but it is typically in the range of 0.5-1.5 days per month.

We will put in place a scalable process to ensure that we are kept appraised of changes to a product and any safety-related incidents which may arise. We will then update the DCB 0129/0160 documentation accordingly.

Clients are provided with email and telephone contact details for their Clinical Safety Officer. Alternative details are provided when the individual is on leave or otherwise unavailable for a period of time.

Service Levels

Safehand cannot guarantee that any safety assessment we conduct will conclude that the product or implementation is associated with an acceptable degree of Clinical Risk. To do so would undermine the assessment process. We do however, at the earliest opportunity, inform our customers of any potential concerns.

Safehand is only able to build reports based on the information disclosed to us by our customers. If the data for the analysis is not provided, it may not be possible to construct a complete report.

Safehand aims to answer all emails and return all calls within 48 hours.

Service Constraints

Our support and office hours are 09:00-17:00 Monday to Friday. The taking of support calls is considered to be effort expended in delivering the project.

Outage and Maintenance Management

Our consultancy services are not dependent on any particular technologies other than Office 365. Our filing systems are hosted by Microsoft on resilient servers in the cloud. Emergency client hardware is always available should an individual workstation fail.

Financial Recompense Model for not Meeting Service Levels

Our services consist of consultancy and cannot realistically be subject to service credits.

4. Provision of the service

Customer Responsibilities

For DCB 0129/0160 drafting services:

The Hazard Log is likely to include a number of testing, training and policy controls. We will need you to trace these to test and other evidence to substantiate the implementation of the controls. We will provide you with the necessary training and templates to do this.

Note that in the event you were unable to provide the evidence needed to construct a valid Safety Case, we would develop the document as far as we were able and produce a work-off plan setting out the remaining activities.

Note that at the start of the project, we cannot guarantee that the Safety Case will conclude that the product is associated with an acceptable degree of Clinical Risk. To do so would undermine the assessment process. We will however, at the earliest opportunity, inform you of any potential concerns.

Strategic support to form local Clinical Risk Management capability:

You will need to appoint a primary point of contact who will take responsibility for establishing the local Clinical Risk Management capability. This individual will need to gain access to other local key personnel such as a potential Clinical Safety Officer and Safety Sponsor.

Technical Requirements and Client-Side Requirements

We will agree the input materials you will provide to us in order to conduct the work. If, in the course of the project, these materials are not forthcoming and/or we receive no communication from you after attempts to contact you by email or telephone, after a period of four weeks, we will archive your project. Dearchiving a project at a later date will incur an additional charge equivalent to one project day of effort, as per the daily rate agreed for the project.

Outcomes/Deliverables
For DCB 0129/0160 drafting services, the deliverables are typically:

- Clinical Risk Management Plan
- Hazard Log
- Clinical Safety Case Report
- Clinical Risk Management Process

Other deliverables may be discussed depending on the precise nature of the engagement.

After-sales Account Management
On-going projects will be allocated to a dedicated Clinical Safety Officer who will look after all aspects of the project on a continuing basis. The Clinical Safety Officer will be contactable by email and telephone. Support hours are between 09:00-17:00 Monday to Friday.

Termination Process
We align with the G-Cloud 15 General Terms regarding no-fault termination clause that Buyers can exercise. As we invoice on a time and materials basis, services will sometimes terminate immediately in practice.

5. Our experience

Case Studies:

ONE LONDON

Through the OneLondon eMHA programme, a new digital tool has been introduced in London to support safer, faster and more joined-up care for people detained under the Mental Health Act (MHA). 2024 saw Safehand Consulting work with six mental health Trusts via the OneLondon eMHA programme to ensure that this new approach, using a digital platform to access, record and share information, was compliant with DCB 0160.

Background

The MHA sets out the legal processes used to assess, treat and detain (if necessary) in a hospital or community setting, people with mental health conditions, often without their consent, to ensure their safety or the safety of others.

In most parts of London, the process for assessing and treating people under the MHA has relied on different staff from different organisations completing and sharing a number of paper-based forms. eMHA by Thalamos supports quicker and more joined-up assessment, treatment and discharge of Londoners detained under the MHA, and OneLondon has supported the deployment of the software in a regional, pan-London programme to improve the experience for patients and clinicians.

While each Trust was required to complete a bespoke safety evaluation under the DCB 0160 Safety Standard, it was recognised that there was an opportunity present for the risk assessment to identify the common themes and implementation measures that would be required across all six organisations.

Safehand provided a Clinical Safety Officer (CSO) to work on behalf of OneLondon to lead a Clinical Safety Workstream, with participation from all six trusts, overseeing the clinical risk management process for the project.

Objectives

- Facilitate compliance with DCB 0160 at six NHS Trusts involved with the programme
- Conduct safety analysis that identified the foreseeable hazards associated with implementing eMHA across the capital
- Evidence the implementation of safety measures where they were provided by the pan-London programme
- Evidence the implementation of the controls that could only be addressed by the participating Trusts themselves
- Produce robust documentation that sets out this systematic approach to clinical safety at both a regional and local level, including a Clinical Risk Management Plan, Hazard Log and Clinical Safety Case Report, and six Deployment-Specific Appendices

The approach

Planning

The risk assessment was planned at a pan-London level, drawing on project documentation relating to the OneLondon programme combined with an engagement process to ensure representation and involvement of the participating Trusts in developing the Clinical Risk Management Plan (CRM Plan).

The CRM Plan identified that:

- Hazard identification would take place in a pan-London approach, with two discovery hazard workshops to draw on the experiences of the full range of multidisciplinary team members involved in the application of the Mental Health Act.
- That each Trust would be responsible for the approval of deliverables and acceptance of clinical risk associated with the deployment.
- That some clinical risk would likely be mitigated by measures being taken at the programme level, and that these would be set out within the main body of the Clinical Safety Case Report (CSCR).

- Clinical risk management workshops would be held at each Trust to consider the localisation work required to implement the remaining controls.

- Evidence of implementation of these localised controls would be set out within a Deployment-Specific Appendix, to accompany the CSCR.

Implementation

Following approval of the CRM Plan by each of the participating Trusts, work throughout the summer of 2024 included the initial discovery workshops and the development of a Hazard Log setting out the identified clinical risks, their causes and the necessary mitigations required for safe use of eMHA by the NHS.

The CSO worked closely with the supplier and the OneLondon team to ensure that the required controls identified informed the work undertaken across the programme. This meant that where possible, controls were implemented at a level which would ensure the greatest reduction in risk, and greatest efficiency, for the programme as a whole. This work captured the clinical risk management activity undertaken at a regional level and was documented within the main CSCR.

In the autumn, the focus shifted to supporting the individual Trusts with their implementation work; ensuring that the safety activity that could only be undertaken at a local level (such as the development of Trust Standard Operating Procedures) were complete and evidence of their implementation was documented. Each Trust had regular access to the CSO to support their programme of work.

Hazard workshops at each Trust identified the local factors that influenced their individual deployments and ensured that their safety assessments accurately reflected the unique circumstances of each organisation.

Outcome

- A Clinical Risk Management Plan that identified an approach that could both deliver economies of scale and risk management that was reflective of each participating Trust's needs.

- A Hazard Log setting out the reasonably foreseeable hazards, their causes and associated controls, with material included to account for the varying use of system functionality and different circumstances at each of the participating organisations.

- A Clinical Safety Case Report setting out the work undertaken regionally, accompanied by Deployment-Specific Appendices evidencing the localised safety work at each Trust.

- Further ongoing support for the programme through the establishment of a Clinical Operations Group responsible for conducting clinical risk assessments of further change management of the product, the monitoring of clinical risk in live service, and shared learning between participating organisations.

OneLondon's view

Working with Safehand Consulting has been positive and supportive. The OneLondon eMHA programme was complex - spanning multiple NHS and social care organisations, all working together to digitise the Mental Health Act. Safehand provided well-planned, pragmatic, thorough and very professional clinical safety oversight and delivery for OneLondon. We recommend their highly skilled and expert guidance and the positive working relationships that they established.

Safehand genuinely works with you, ensuring clinical safety compliance is achieved and embedded. They played a vital role in helping us introduce the new digital system that is now supporting safer, faster, and more joined up mental healthcare in London. Thank you!

- Joss Palmer, OneLondon Programme Director

Leading this work has only been made possible by having experts on hand to deal with specialist areas. Safehand has brought the necessary expertise and managed all the detailed aspects of Clinical Safety. It has been a pleasure to work alongside Alex.

- Nina Schmidt-Marino, Head of Digital Strategy and Planning London Region NHSE; Pan-London lead for OneLondon eMHA programme

Clients

A number of up to date testimonials and case studies are available on our website, safehand.co.uk > About Us > What Our Customers Say

A selection of our clients are set out below:

SiLiCON PRACTICE	KLINIK HEALTHCARE SOLUTIONS	NHS The Christie NHS Foundation Trust
attendanywhere	Black Country Partnership NHS Foundation Trust	DOC Abode

NHS The Leeds Teaching Hospitals NHS Trust	NHS University Hospitals of Leicester NHS Trust	NHS North East London
NHS Gateshead Health NHS Foundation Trust	NHS Midlands and Lancashire Commissioning Support Unit	NHS Kingston Hospital NHS Foundation Trust
TERRAFIX	MaST	NHS Greater Glasgow and Clyde
Black Country Partnership NHS NHS Foundation Trust	NHS University Hospitals of Derby and Burton NHS Foundation Trust	Dental Referrals
ashtons HOSPITAL PHARMACY SERVICES		NHS Dartford and Gravesham NHS Trust
NHS Islington Clinical Commissioning Group	NHS Gloucestershire Clinical Commissioning Group	<sitekit>

NHS Buckinghamshire Healthcare NHS Trust	4S DAWN	OMRON
InterSystems	Shiny Mind	mahana™
NHS Northumberland, Tyne and Wear NHS Foundation Trust	NHS University Hospitals Dorset NHS Foundation Trust	tellmi
clinicalcomputing	TCR Nottingham Ltd	NHS East Sussex Healthcare NHS Trust
MEDILOGIK ems ENDOSCOPY MANAGEMENT SYSTEM	SOFT OPTIONS	

Table of client logos

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