

#### **Executive Summary**

## The Developer's Imperative

Building digital health technology for the NHS is about more than just meeting regulations. It's about protecting patients, earning clinical trust and making security and data integrity a core part of the process from the outset.

This guide breaks down complex NHS frameworks and policies into clear, practical steps for developers. It shows how to build security and resilience into a product's DNA – not just at launch, but throughout its lifecycle.

The shift we're seeing is a move away from box-ticking compliance towards continuous assurance. With the NHS adopting the NCSC Cyber Assessment Framework, developers are expected to prove that security is real, embedded and ongoing.

That's where approaches like DevSecOps and "shift-left" come in. By weaving security into every stage of development, teams can spot and fix vulnerabilities early, rather than scrambling to react later.

The result is software that's inherently more resilient, designed to withstand today's evolving cyber threats and to keep patients safe.

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# Part | The Regulatory and Compliance Foundation

NHS software must be safe, legal and clearly evidenced before it goes live. Focus on protecting patient data, managing clinical risk and showing how you do this in practice. Know the basics: UK GDPR, DTAC for buying checks, DSPT for data protection and a named Clinical Safety Officer. Get these right and approvals move faster, audits are smoother and buyer trust increases.

#### **Chapter 1**

## Navigating the NHS Digital Landscape

#### 1.1 The NHS's Strategic Vision and Security Imperative

Security of any NHS IT system, service, or application is defined as "priority zero". The UK government's Cyber Security Strategy for Health and Social Care sets an ambitious objective to achieve a fully digitised healthcare system by 2030, a monumental goal that necessitates an "ironclad security foundation". From a developer's perspective, this means a product is not an isolated piece of software but an integral component of a vast and interconnected national infrastructure. A security vulnerability in a single product can have far-reaching consequences, disrupting critical patient care, causing financial losses, and eroding the public's trust in the healthcare system. Therefore, a developer's role is to ensure their product is a trustworthy and resilient component that reinforces the security of the entire ecosystem.

### 1.2 The Data Security and Protection Toolkit (DSPT): Your Market Entry Pass

The Data Security and Protection Toolkit (DSPT) is a compulsory online self-assessment that all organisations with access to NHS patient data, NHS systems, or an NHS contract must complete annually. The toolkit is designed to allow organisations to measure their performance against the National Data Guardian's ten data security standards. The primary goal for a new developer is to reach the "Standards Met" level, which requires completing a minimum of 43 evidence items and providing supporting documentation. The toolkit serves as a critical trust layer. As of 2024, select organisations are now required to undergo an independent audit for DSPT compliance, signalling the increased rigour of the assessment. This means developers must ensure their technical controls are not merely self-attested but are well documented and verifiable to withstand external scrutiny.

### 1.3 Cyber Essentials Plus (CE+): The Foundational Technical Baseline

The Cyber Essentials (CE) scheme is a UK government-backed initiative that provides a straightforward set of technical controls to protect organisations from common cyber threats.

While a basic CE certification is a self-assessment, Cyber Essentials Plus (CE+) offers a higher level of assurance through a rigorous, independent technical audit. This makes CE+ the preferred option for NHS and healthcare organisations that handle highly sensitive patient data.

The CE+ certification assesses an organisation's implementation of five key technical controls:

#### 1. Firewalls

The secure hardening of all internet-facing firewalls is required to prevent unauthorised network access.

#### 2. Secure Configuration

Systems and software must be securely configured to minimise the attack surface, utilising authentication and encryption.

#### 3. User Access Control

An effective user access control mechanism must be in place to limit access to sensitive data and systems based on a user's need for that data. This aligns directly with the principle of least privilege.

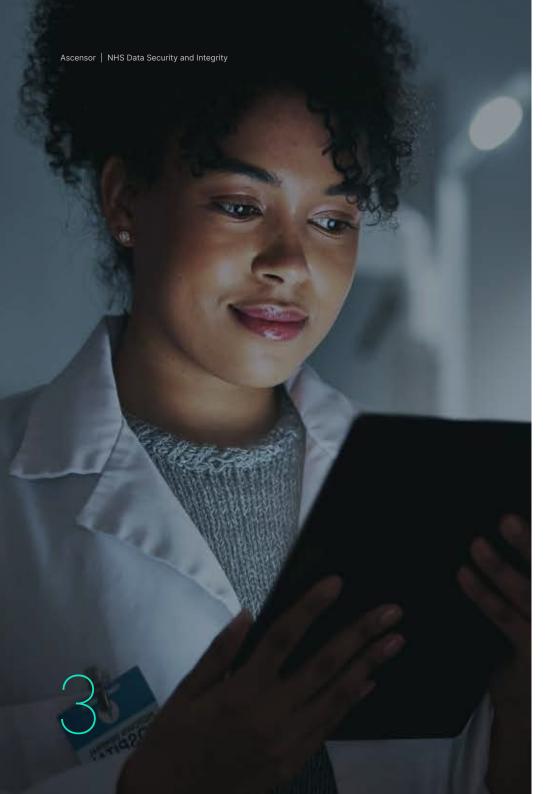
#### 4. Malware Protection

Endpoint protection against malware must be implemented to reduce and limit the likelihood of infections.

#### 5. Patch Management

Organisations must demonstrate an effective process for fixing software vulnerabilities. This includes a strict 14-day window for patching high-risk vulnerabilities.

The compliance cascade demonstrates the interconnectedness of these frameworks. A CE+ certificate provides a robust technical baseline that directly addresses many of the questions asked in the DSPT self-assessment, significantly reducing the administrative burden and compliance effort. Furthermore, a CE+ certificate is a prerequisite for a product's technical security assessment under the Digital Technology Assessment Criteria (DTAC). Therefore, securing CE+ certification is the most strategic and efficient starting point for any health tech developer aiming to enter the NHS market, as it creates a chain reaction of trust and assurance recognised by multiple governing bodies.



### 1.4 The Digital Technology Assessment Criteria (DTAC): A Market Readiness Check

The Digital Technology Assessment Criteria (DTAC) is a set of criteria used by NHS organisations when assessing new digital technologies for implementation. DTAC serves as a minimum standard across several key areas, including clinical safety, data protection, and technical security. For a developer, successfully meeting DTAC's technical security requirements is a crucial step towards market readiness. These requirements include demonstrating possession of a CE+ certificate, conducting regular penetration testing, performing a custom code review, implementing multi-factor authentication (MFA), and maintaining robust logging and reporting capabilities.

#### **Chapter 2**

## The Cornerstone of Data Privacy: UK GDPR

#### 2.1 Data Protection by Design and by Default

The UK GDPR requires a "privacy-first" approach, mandating that developers integrate data protection into every aspect of their processing activities from the earliest design phases. This goes beyond merely adhering to a set of rules and instead requires actively choosing technical and organisational measures to embed privacy into the core functionality of a system. For developers, this means the system must be designed to protect personal data automatically, without the user having to take any specific steps. Practical examples include pseudonymising personal data as soon as possible and ensuring transparency about how personal data is processed. The ICO's guidance is specifically written to help technology professionals understand how to incorporate these principles into their development lifecycle.

#### 2.2 Data Minimisation in Practice

The principle of data minimisation dictates that the personal data processed must be "adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed". This is particularly important for special category data, such as health information, which is considered highly sensitive. Developers must build systems that identify the minimum amount of personal data needed to fulfil a stated purpose and do not collect or hold any more than is required. This principle is closely linked to the storage limitation principle, which requires data to be securely deleted once its purpose has been fulfilled. Adherence to this principle is a key part of the accountability framework, requiring organisations to demonstrate that they have appropriate processes in place to comply.

#### 2.3 Engineering Individual Rights

Developers are legally obligated to build system features that support an individual's rights under the UK GDPR. This includes the right to access, rectify, and erase personal data. These rights are not abstract legal concepts; they must be translated into tangible, user-facing functionalities. The product must have clear consent management mechanisms and provide users with an easy process to exercise their rights. Furthermore, in the event of a data breach, a protocol must be in place to notify both stakeholders and the Information Commissioner's Office (ICO) within 72 hours. Documenting all data processing activities, including the types of data collected and with whom it is shared, is also a critical part of the developer's responsibility.

#### Part II

# The Secure Software Development Lifecycle (SSDLC) in Practice

#### **Chapter 3**

## **Shifting Security Left: Design and Requirements**

#### 3.1 Fostering a DevSecOps Culture

The modern approach to security is not a separate function but an integral part of the development process. This "shift-left" approach moves security prevention closer to the source of change, turning feedback loops inward and empowering development teams to address vulnerabilities as they write code. This is a strategic imperative outlined in the NCSC's "Secure development" principle, which calls for a robust, automated, and audited integration and deployment pipeline. The transition to a DevSecOps culture requires a proactive, collaborative approach between security and development teams, often facilitated by extensive training and a shared understanding of security expectations. This collaborative mindset transforms security from a late-stage project roadblock into a continuous enabler of both speed and reliability.

#### 3.2 Threat Modelling for Health Tech

Threat modelling is a foundational activity that must take place during the design phase. It is the critical "control point" where architectural decisions are made that either enable secure behaviour or hardwire systemic weaknesses into the product. Neglecting this step risks embedding attack paths into the blueprint of the application before a single line of code is written. A practical process for threat modelling involves several key steps: a developer should start by creating data flow diagrams to map trust boundaries, privilege levels, and all external input sources. Throughout this process, a "zero-trust" model should be assumed, where no actor or system is implicitly trusted. The team should then define "abuse cases" - hypothetical misuse scenarios - to force early visibility into how a feature could be subverted, allowing them to define mitigation pathways and specific security requirements upfront.

#### 3.3 Defining Security Requirements

Security requirements must be expressed with the same rigour as functional stories. Vague statements are insufficient; security user stories should carry specific acceptance criteria that are tied to verifiable behaviours, creating a direct link between the intent of the design and the enforcement of controls. For example, a requirement to securely manage credentials would translate into a specific, testable technical requirement, such as "Secrets must never reside in source code". Similarly, the NHS GP Connect API security guidance provides a perfect example of this rigour, mandating that consumer and provider systems "MUST only accept encrypted connections" over TLSv1.2 and must drop all insecure attempts. Translating these high-level mandates into specific, verifiable requirements is a core competency for any developer operating in the NHS space.

#### **Chapter 4**

#### **Secure Implementation & Hardening**

#### **4.1 Secure Coding Best Practices**

The coding phase is where security policy must become concrete behaviour. Without enforced guardrails, developer intent alone cannot sustain a strong security posture. Secure coding standards should exist at the language and framework level, with dangerous functions and pattern-level anti-patterns treated as break conditions rather than advisory warnings. Static code analysers (SAST) should be used to flag violations early, and secrets, such as credentials, must never reside in the source code. A developer's focus must also be on preventing common vulnerabilities. This includes sanitising all inputs to prevent injection attacks (e.g. SQL/NoSQL injection, Cross-Site Scripting) and implementing a database query abstraction layer (ORM) to handle queries securely. The OWASP Top 10 provides a canonical reference for these good coding practices.

#### 4.2 Secure API Design

APIs, especially those handling sensitive patient data, are a primary attack vector and require robust security. Best practices include placing all APIs behind a gateway to centralise security features like rate limiting and logging. Furthermore, a centralised OAuth authorisation server should be used to issue and manage access tokens, rather than allowing individual APIs to handle this complex process. The Fast Healthcare Interoperability Resources (FHIR) API is the standard for health data exchange, but its security is not "baked-in" by default. While FHIR provides a framework for data exchange, a developer must actively implement security layers. NHS Digital's own documentation shows that some FHIR APIs can be used "with or without access controls", a critical point of failure that must be addressed by the developer. The following table provides a detailed checklist for building a secure FHIR API, linking common vulnerabilities to specific mitigation strategies that a developer must implement.

#### 4.3 Cryptography and Secrets Management

All health data must be protected by encryption, both when it is in transit (transferred across networks) and when it is at rest (stored on servers). For data in transit, the NHS GP Connect API security guidance mandates the use of TLSv1.2 and specifies a list of required cyphers, including AESGCM+EECDH, AESGCM+EDH, AES256+EECDH, and AES256+EDH. For data at rest, the recommendation is to use AES-256 encryption for databases and backups. The secure management of the encryption keys is equally critical; they should be securely managed using cloud key management systems (KMS) or hardware security modules (HSMs).

Table: A Developer's Checklist for FHIR API Security

Vulnerability / Risk	Technical Mitigation Strategy
Lack of end-to-end encryption	Enforce HTTPS for all data transfers using TLSv1.2 or higher. Use strong cyphers and reject all non-HTTPS requests.
Unauthorised / Unauthenticated access	Implement robust authentication mechanisms such as OAuth 2.0 and OpenID Connect for identity verification. Consider MFA for all administrative users.
Over-privileged access	Apply the principle of least privilege. Use fine-grained access control with FHIR scopes (e.g., patient/Observation.read) to limit token permissions.
Data tampering during transit	Ensure data integrity using cryptographic checksums and JSON Web Tokens (JWTs) for signed claims. Validate resource provenance in audit trails.
Lack of traceability and accountability	Implement comprehensive audit logging using the FHIR AuditEvent resource. Store logs in a secure, tamper-proof system, separate from other data.
Compromised credentials via insecure storage	Never store client secrets in code. Use a server to hide client secrets and use a central OAuth server for token issuance.
Malicious code injection from FHIR narrative field	Scrub out all active elements from FHIR narrative HTML, such as onclick or onhover. Do not trust external URLs or run unknown code.

#### **Chapter 5**

## Continuous Assurance: Testing, Deployment, and Operations



#### **5.1 Automated Security Testing**

Security is a continuous process that is best served by automation. The NCSC's guidance on secure development calls for an automated and audited integration and deployment pipeline, and security functions best when it is integrated into every phase. This includes the use of automated testing tools such as Static Application Security Testing (SAST) to check for unsafe code paths and insecure functions, Dynamic Application Security Testing (DAST) to simulate adversarial behaviour on APIs and web frontends, and Software Composition Analysis (SCA) to identify vulnerable third-party libraries and licence violations. These tools provide rapid, repeatable security feedback to developers before code is deployed.

#### **5.2 Penetration Testing and Vulnerability Management**

Automated testing is a critical baseline, but it is not a complete solution. NHS or healthcare organisations are required to undertake an approved IT Health-check/Penetration Test on an annual basis for their cloud services, including any edge connections to the internet. These tests should be performed by certified companies or testers, such as those registered in the CREST or CHECK schemes. In addition to these formal audits, proactive measures such as running bug bounty programmes can be highly effective in identifying vulnerabilities by leveraging a community of security researchers.

#### **5.3 Operational Security and Incident Response**

Once a product is live, services must be operated and managed in a way that actively impedes, detects, and prevents attacks. This requires a comprehensive monitoring strategy, with live services teams constantly monitoring the product 24/7 to quickly identify and fix any issues. All user activity on the platform must be logged and monitored for suspicious activity, and security logs must be encrypted and stored in a secure, tamper-proof system, isolated from the rest of the application data to prevent attackers from covering their tracks. Developers must also have a clear incident response and business continuity plan in place to deal with unexpected events and minimise disruption.

# Part III **Technical Controls & Advanced Topics**

#### **Chapter 6**

### **Protecting Health Data in the Cloud**

#### **6.1 Implementing NCSC Cloud Security Principles**

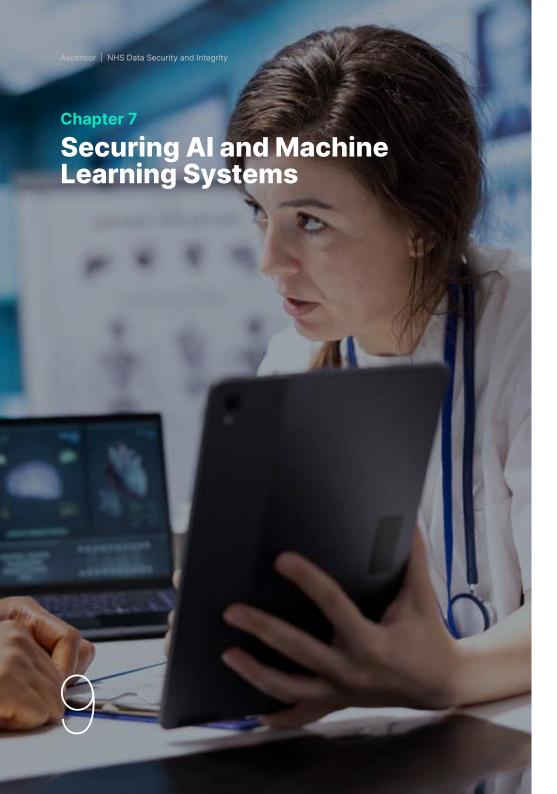
The NHS has adopted the NCSC's 14 Cloud Security Principles as the guiding framework for securing cloud services. These principles are not merely abstract concepts; they translate into a set of concrete, actionable technical controls that developers must implement. Adherence to these principles is essential when using major cloud providers, such as Amazon Web Services (AWS) or Google Cloud Platform (GCP), for NHS data. The following table maps several key NCSC principles to a developer's responsibilities.

#### 6.2 Identity and Access Management (IAM)

Identity and Access Management is a cornerstone of cloud security. The NHS Cloud Security Guidance mandates that access to public cloud-deployed platforms must be on the basis of "least privilege". The principles of least privilege and "need-to-know" must be rigorously enforced through role-based access control (RBAC). This means that access to a system and its data is constrained to only what is necessary for an individual's role. It is a mandatory requirement to have Multi-Factor Authentication (MFA) available and enforced for all cloud services.

#### Table: NCSC Cloud Principles in Action

NCSC Principle	Developer's Technical Implementation
Data in transit protection	Implement and enforce TLSv1.2 or higher with NHS-mandated cyphers. Require TLS protection for all data transfers.
Asset protection and resilience	Encrypt all data at rest using strong encryption algorithms like AES-256. Use a cloud-native Key Management System (KMS) or a Hardware Security Module (HSM) to manage encryption keys securely and separate them from the data they protect.
Separation between customers	Design the service with clear trust boundaries between tenants and implement micro-segmentation of the network. Use effective security boundaries in the way code is run, data is stored, and the network is managed.
Secure development	Embed a robust, automated, and audited integration and deployment pipeline. Implement a "shift-left" approach to security, ensuring security is integral to the development process rather than a final step.
Identity and authentication	Implement Multi-Factor Authentication (MFA) for all cloud service access. Use a central identity provider for federated access based on user roles.
Secure user management	Make tools available for securely managing user accounts and permissions, adhering to the principle of least privilege. Ensure it is easy to remove permissions when no longer required.
Secure service administration	Carefully manage privileged access to administrative systems. Implement detailed privileged access logs suitable for a later audit.
Audit information for users	Provide audit records for users to monitor access to their service and data. The type of audit information provided directly impacts the ability to detect and respond to inappropriate or malicious activity within a reasonable timescale.



Safe AI starts with safe data. Govern training sets, remove bias and monitor drift so models stay explainable and clinically reliable.

#### 7.1 Governance and Risk Management for Al

The NHS is actively encouraging the use of AI to tackle major healthcare challenges, but with a strict Code of Conduct to ensure only the safest and most secure systems are used. The international standard ISO/IEC 42001, introduced in December 2023, is considered best practice for organisations developing and using AI systems in healthcare. Adherence to this standard demonstrates to the NHS that an AI technology has been responsibly developed, implemented, and maintained in compliance with legal and ethical standards. It also shows that AI-specific risks, such as security, safety, fairness, and data quality, are being managed effectively throughout the system's lifecycle.

#### 7.2 Bias Mitigation and Data Integrity

The ICO's guidance on AI focuses on core data protection principles like fairness and accuracy. A developer's technical choices, from the selection of the training dataset to the modelling abstractions used, have a direct and profound impact on the fairness and accuracy of the system. This creates a causal relationship: a technical flaw, such as a biased dataset, can lead to a legal and ethical violation under the UK GDPR. The solution is not merely about writing secure code but also about ensuring the integrity and quality of the data and the fairness of the algorithm from a technical perspective. The ICO's guidance provides technical approaches to mitigate algorithmic bias and emphasises that developers must consider issues of fairness throughout the entire AI lifecycle, from problem formulation to decommissioning.

#### 7.3 Data Quality and the Supply Chain

Data quality is paramount for AI systems, and the integrity of the data pipeline is a major security concern. The NHS's Federated Data Platform (FDP) simplifies secure data collection, but a developer's reliance on third-party APIs or data sources for AI model training introduces risk. Supply chain vulnerabilities are a well-documented top risk in the UK healthcare sector, and attackers can exploit weak links to gain unauthorised access. The NCSC's "Supply chain security" principle demands that all third parties, including data and software suppliers, meet the same security standards that an organisation sets for itself. This places the onus on the developer to perform due diligence on all third-party vendors and ensure that contracts include security responsibilities and incident response procedures.

#### Conclusion

## Building Trust and Future-Proofing Your Product

The transition to a fully digitised NHS is underway, and with it comes a heightened demand for security, integrity, and trust. For the health tech developer, this means a security-first approach is not a regulatory hurdle to be cleared but a strategic investment in the longevity and success of their product. This guide has demonstrated how to build a product that is not only compliant with UK frameworks like the DSPT, CE+, and DTAC but is also resilient to the evolving threat landscape.

#### The pathway to achieving this resilience is clear

Start by establishing a strong technical baseline with Cyber Essentials Plus certification. From there, adopt a continuous assurance mindset by embedding security into every phase of the software development lifecycle, from threat modelling at the design stage to continuous monitoring in operations. Finally, understand that every technical decision, from the encryption cypher used for data in transit to the integrity of an Al training dataset, has a direct impact on legal obligations and the fundamental trust placed in your product by the NHS and its patients. The future of health tech is not just about innovation but about building an ecosystem that is fundamentally secure and reliable.

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