



## Quality at TrakCel: Meeting HIPAA Compliance

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Advanced technologies are continuing to transform healthcare. Securing all the data that is captured by these technologies and ensuring compliance with industry standards can be challenging.

Learn how TrakCel can help regulated companies enforce strong security policies and mitigate risks around the deployment, maintenance and support of your new TrakCel system.

# > what is HIPAA?

## What is HIPAA?

HIPAA is a US Act that protects the security of Personal Health Information and against its misuse.

HIPAA consists of two parts:

- Privacy Rule
- Security Rule

## What is Personal Health Information (PHI)?

There are 18 identifiers of Personal Health Information PHI (HIPAA SEC. 1173 (b)) >

1. Names,
2. Geographical subdivisions,
3. All elements of dates,
4. Telephone numbers,
5. Facsimile numbers,
6. Electronic mail addresses,
7. Social security numbers,
8. Medical record numbers,
9. Health plan beneficiary numbers,
10. Account numbers
11. Certificate/license numbers,
12. Vehicle identifiers,
13. Device identifiers,



14. Web universal resource locators (URLs)
15. Internet protocol address numbers,
16. Bio-metric identifiers,
17. Full-face photographic images,
18. Any other unique identifying numbers



## > the Privacy Rule

### What is the Privacy Rule?

HIPAA grants patients certain rights:

**Right of Access:** A patient has the right to request a copy of their stored health information. An organisation must present a copy within thirty days of request.

**Right of Amendment Request:** A patient has the right to ask for a change of records, which may or may not be accepted by their doctor

**Right of Accounting for Disclosure:** Patients can request disclosures relating to with whom their information is shared.

**Right to Restriction:** Patients may opt to restrict the disclosure of their PHI.

### Meeting the Privacy Rule

**Right of Access:** TrakCel allows PHI data to be exported or printed in a human readable form.

**Right of Amendment Request:** Access to change patient ePHI is defined by customer's user access policies and enforced by TrakCel.

**Right of Accounting for Disclosure:** TrakCel will provide data flows for PHI data.

**Right to Restriction:** TrakCel utilises an anonymised patient ID that abides by HIPAA and EU regulation to be used to track cellular materials throughout the treatment process and ensure that the right treatment reaches the right patient without exposing ePHI to third parties.



## > the Security Rule

### What is the Security Rule?

Establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity.

Requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information.

### Meeting the Security Rule

**Administrative Safeguards:** TrakCel works with its customers to ensure that the appropriate SOPs, training and documentation is in place.

**Physical Safeguards:** TrakCel will work with its customers to ensure that access to the physical machines storing the ePHI (including machines used for backup and archiving) is restricted.

**Technical Safeguards:** TrakCel uses access controls, encryption and logging to ensure that sensitive data is secure.



> TrakCel will support its customers when it comes to risk management.

### Risk Management

TrakCel will support its customers when it comes to risk management.

Risk management should include the evaluation of:

- Physical risks: How the information is stored
- Administrative risks: What procedures are in place to protect information,
- Technical risks: The electronic measures in place to protect data.

Risk analysis undertaken by TrakCel will address risks to confidentiality, integrity and availability of the patient's information whilst evaluating risks and vulnerabilities..

### Notification of Breach

Notification must be made to the Secretary of HHS within 60 days of any breach (if the data of over 500 patients has been affected)increases.

TrakCel will provide support to its customers in the event of a breach to investigate:

- What type of breach occurred
- What ePHI was involved
- What safeguards were in place
- What action should be taken in response to the breach.

### Required Documentation

TrakCel will support its customers in the creation or update of the following documentation required by HIPAA (if these are not already in place):

- Implementation specifications
- Contingency operations
- Facility security plan
- Access control and validation procedures
- Procedures to document any modifications to PHI data housing that may affect the facility's security

For more information on TrakCel's commitment to quality, please see the following documentation:

- TrakCel - 21 CFR Part 11 – Regulatory Alignment
- TrakCel - Product Quality Plan
- TrakCel - Customer Project Quality Plan

# TrakCel

10/11 Raleigh Walk  
Brigantine Place  
Waterfront 2000  
Cardiff, UK

[www.trakcel.com](http://www.trakcel.com)