DTAC – Frequently Asked Questions

What is DTAC?

DTAC stands for **Digital Technology Assessment Criteria**.
It is the NHS framework used to assess whether a digital health product is **safe, secure, clinically governed, interoperable, and usable** before it is deployed in healthcare settings.

DTAC is defined by **NHS England** and is widely used by NHS organisations as part of digital assurance and procurement.

Is DTAC a certificate or accreditation?

No.
DTAC is **not** a certificate, badge, or one-off approval.

DTAC is an **evidence-based framework**. Suppliers are expected to:

- Hold appropriate documentation
- Demonstrate compliance when requested
- Update evidence as products evolve

There is no central DTAC “approval” or public register.

Does DTAC apply to companies or products?

DTAC applies to **individual digital products**, not to companies or platforms as a whole.

Each product or clinical application is assessed based on:

- Its intended use
- Its risk profile
- How and where it is deployed

How does DTAC apply to PharmBot AI?

PharmBot AI is a **platform** that hosts multiple clinical and operational applications.

DTAC is applied **at the product level**, not the platform level.

We currently maintain a **full DTAC evidence pack for AIVAe**, our clinical decision support application.
Other modules are assessed **individually** as they enter clinical use.

Which DTAC areas are covered?

DTAC consists of five pillars:

1. **Clinical Safety**
2. **Data Protection & Privacy**
3. **Technical Security**
4. **Interoperability**
5. **Usability & Accessibility**

For AIVAe, all five areas are addressed with documented evidence.

Is PharmBot AI “DTAC compliant”?

We use the term **DTAC-aligned**, not “DTAC certified”.

For AIVAe, this means:

- A defined DTAC scope
- Clinical safety documentation (DCB0129)
- Data Protection Impact Assessment (DPIA)
- Technical security controls aligned with NHS expectations
- Usability, accessibility, and interoperability statements

This evidence is available for review by NHS partners.

Do you submit DTAC centrally to the NHS?

No.
There is **no central DTAC submission process**.

DTAC assurance is typically:

- Requested by an NHS organisation (Trust, ICB, pilot partner)
- Reviewed locally as part of procurement or deployment
- Supported by supplier-provided evidence

Where required, we complete the DTAC self-assessment as part of a local assurance process.

Does DTAC replace MHRA or UKCA requirements?

No.
DTAC and medical device regulation serve **different purposes**.

DTAC focuses on:

- Digital assurance
- Clinical safety
- Information governance
- Operational readiness

Regulatory requirements (e.g. MHRA, UKCA) are assessed separately and only apply where relevant.

Why does PharmBot apply DTAC on a module-by-module basis?

Because this is how the NHS expects digital systems to be governed.

Different modules:

- Carry different levels of risk
- Serve different clinical purposes
- May be deployed in different contexts

Applying DTAC proportionately ensures:

- Safer deployment
- Clear accountability
- Faster adoption where appropriate

Can NHS partners review your DTAC documentation?

Yes.
We provide DTAC documentation **on request** to NHS organisations, commissioners, and pilot partners, and we work collaboratively to meet local assurance requirements.

How often is DTAC evidence reviewed?

DTAC documentation is reviewed:

- When a product changes materially
- Before wider deployment
- As part of ongoing clinical and information governance
- At least annually during active use

Summary

- DTAC is an NHS digital assurance framework
- It is evidence-based, not certificate-based
- It applies to products, not platforms
- AIVAe is DTAC-aligned with a full evidence pack
- Other PharmBot modules are assessed as they enter clinical use