|  |
| --- |
| HAMILTON LAW SCIENTIFIC |
| HEALTH TECH LEGAL CHECKLIST  |
| **You have picked a wonderful sector and we are truly excited to see what you will do. But you will already know that it is a complex path ahead. Consider these simple topics before your major milestones.** **No promise that the answer is simple, but the right questions are a good start.** **What we can guarantee is that interested individuals will ask some or all of these questions, so get your answers ready!** |
| **Just checking, are your suppliers definitely happy with the use case?** * Think of suppliers as broadly as possible. Anyone doing anything for you or giving you anything.
* Check contractual freedom in supplier terms. No-one likes surprises.
* Check provider terms protect you sufficiently from IP infringement, defects and specific points of concern.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**Are you dealing directly with individuals?** * Consider what contractual relationship you will have with individuals, if any, or if you need to directly give them notice of anything. A good notice can be a legal risk mitigation measure.
* Check consumer law compliance.
* Check contractual relationship with NHS/customer organisations. Appropriate contractual commitments and permissions should be in place and your relationship with individual patients should be consistent with them.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT [ ]  |

**Have you thought about the digital health risk of dealing with individuals directly?** * If you have an app, prepare app use terms and consider contractual relationship with app marketplaces and distributors.
* Consider whether CMA, CQC or relevant ombudsman says anything about interactions with health consumers.
* Take a step back and consider user experience, ethics and reputation risk.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**Are you conducting research? Do you need to conduct research to support your plans? How do you find participants?** * Compare what you are doing to accepted definition of “research”. Reach conclusion and verify with expert.
* Check regulatory requirements relating to clinical investigations or performance evaluations. Map out pre-market compliance requirements.
* Work out if you need approval from the NHS (the requirement is probably more broad than you think).
* Work out if you need approval or a positive opinion of a Research Ethics Committee (REC).
* Design recruitment and onboarding processes that respect participant autonomy, secures valid consent, and is defensibly ethical.
* Confirm use of personal data as lawful under direct marketing and privacy laws.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**You developed it yourself! Wow. So you own the system?** * Check history of development and confirm IP ownership in principle.
* Check IP registries and wider use of IP and technology.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**What could actually go wrong? Every device/solution has some issues. Have you identified them all yet? How can you be sure about that? OK, so there are a few issues, but what is being done about them and who’s doing it?*** Brainstorm problem scenarios. Focus of situations that could cause financial loss or injury.
* Review data on performance and user experience, if there is any. If not, generate it.
* Carefully consider impact of known issues and design effective mitigating measures.
* Consider NHS guidance or other relevant standard on clinical risk.
* Get an independent clinician to review risks and mitigations.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**You are likely to need to present supporting data for adopters or for a health technology assessment. Is that in hand?** * Check data and do gap analysis.
* Check for any restrictions on use of data.
* Engage an independent expert and ask them to confirm or challenge your conclusions.
* Consider published data/evidence requirements of NICE, if applicable.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**What do we need in our customer contracts?** * Do a risk identification exercise and consider appropriate allocation of risks.
* Check your insurance coverage.
* Make sure your commercial model is clear.
* Check to see what other businesses are doing.
* Check with contract lawyer.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**You are going to need to watch things carefully. Do you have a plan for that? And if you need to change things, it might not be totally straight-forward. Have you got a plan for changes too?** * Post-market plan.
* Change management plan.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**If you have a physical product, have you established a long-term supply chain with all supplier contracts giving you security of supply.*** Suppliers can’t terminate or raise prices too easily.
* Suppliers help you out quickly if problems arise.
* You can build redundancy into the system if needed.
* If supplying to the NHS, suppliers have all agreed to meet NHS standards.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

 | **How are you presenting your solution? Will users understand and stick to that message? Are you allowed to market it in that way?*** Consider risk of users straying from instructions. Design mitigations.
* Carry out an advertising law and contractual commitment check.
* If it’s a regulated medical device, comply with law and regulatory guidance on advertising and product presentation (including instructions and claims).
* Check your presentation doesn’t trigger application of regulation.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**There is a difference between regulated products with a medical purpose and health-related products and services that may play an important role but not in the clinical sense. Have you done that assessment? Are you sure? Why?*** Regulatory assessment and confirmation by independent expert.
* Identify relevant guidance relating to borderlines and activities that could affect status of product.
* Liaise with regulators if unsure, but approach with caution.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**Is the system and related data secure? That’s great to hear, but how do we actually know that?** * Check whether the system is vulnerable to security breaches (however they might happen).
* Now check that an independent third party expert agrees with you.
* Consider concerns about input data being at risk and the importance of the data.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**People are going to put data into the system. What happens to the data? Is confidential information (like medical records) at risk?** * Check the IT architecture and work out where inputs go.
* Be ready to reassure customers and users about protections in place.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**Do you have access to electronic medical records? How did you secure that? How did the integration process go?** * Check relevant agreement with healthcare organisation.
* Check reliance on systems that are not in your control and ensure risk is allocated appropriately.
* Check technical standards have been met.
* Sandbox and live testing completed.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**Your device/solution will need to work together with customer systems. Is it compatible? Does it meet interoperability standards?*** Check NHS requirements, if relevant. Confirm ability to comply.
* Consider risk of systems being changed.
* Check whether interoperability requires use of another business’s specific technology.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**Have you found an organisation that is willing to do a pilot with your tech?** * Agree terms for the pilot.
* Check access and ownership of pilot outputs. Take care to avoid blocking future plans or becoming tied to pilot organisation.
* Make sure you can use the data to develop your tech and convince other customers to get onboard.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**The device/solution will collect and process personal data. Is that allowed?*** Check who determines what happens to personal data, who processes it, and where.
* Consider privacy risks for individuals.
* Identify relevant ICO guidance and design compliance measures.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**Are you providing any kind of healthcare service through your technology or in parallel? Have you considered whether healthcare regulation applies?** * Confirm whether CQC registration is required. If so, obtain registration (not to be underestimated).
* Check insurance covers clinical negligence.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**The use of the device/solution will generate some really valuable data. What will you use it for and are you allowed to do that?** * Check that customer/user terms allow for intended data use.
* Consider privacy implications of data use.
* Assess ownership of collected data and determine whether you are permitted to exploit or even sell the data.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

**Do you know who your buyer is, or what type of organisation they are likely to be? And have you seen the terms they normally want to impose?** * Identify the routes by which your product/solution can be purchased.
* Check the available published contracts and confirm compliance.
* Check for existing and prospective frameworks and get ready to win a place on the framework and win in competition with other framework suppliers.
* Prepare in advance to negotiate points that are not acceptable.
* Draft standard terms for requests that are either private sector or fall outside procurement rules.

|  |  |  |
| --- | --- | --- |
| Discussed [ ]  | Uh oh… [ ]  | Happy HT[ ]  |

 |

|  |
| --- |
| **COMPLIANCE CHECK** |
| * Medical Devices Regulations 2002
 | [ ]  |
| * MHRA and EMA/Commission guidance for medical devices.
 | [ ]  |
| * ISO13485 or equivalent QMS standard
 | [ ]  |
| * NHS DTAC
 | [ ]  |
| * NHS DSP toolkit
 | [ ]  |
| * OWASP
 | [ ]  |
| * UK GDPR and DPA2018
 | [ ]  |
| * The Privacy and Electronic Communications (EC Directive) Regulations 2003
 | [ ]  |
| * ICO guidance
 | [ ]  |
| * Confidentiality, CAG and section 251 of the NHS Act
 | [ ]  |
| * HRA / HCRW
 | [ ]  |
| * REC (and ethics more generally)
 | [ ]  |
| * NICE evidence standards
 | [ ]  |
| * NHS Digital – clinical risk-management standard / ISO14971
 | [ ]  |
| * DHSC guide to good practice for digital and data-driven health and care technologies
 | [ ]  |
| * Care Quality Commission
 | [ ]  |
| * Consumer law
 | [ ]  |
| * Procurement Act 2023
 | [ ]  |
| * Insurance policy
 | [ ]  |

|  |
| --- |
| **HEALTH TECH CONTRACTS**1. **Consumer goods and services agreements**
2. **Public sector procurement – goods and services agreements / frameworks and call off contracts**
3. **Data processing/sharing agreements**
4. **App terms**
5. **Research/development services agreements**
6. **Data access licences**
7. **Pilot agreements**
8. **Collaboration agreements**
9. **Manufacturing agreements**
10. **Distribution agreements**
11. **Consent forms**

**…and more** |
| HOW CAN HLS HELP?  |
| ***Contract drafting and negotiation.******Regulatory guidance.*** ***Special arrangements and packages for early-stage businesses and UK ventures.*** ***Consultancy arrangement for professional services firms (under our name or yours)******Project, seasonal and overflow support for in-house legal teams.*** |