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| 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 | |

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| **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 |  |

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| **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.*** |