HEMPSONS

Digital Newsbrief

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Welcome

Welcome to the summer edition of Hempsons' digital newsbrief, providing an update on a range of commercial and legal issues as well as a focus on current clients of Hempsons.

Hempsons' digital team has particular expertise in supporting the key role technology and innovation play in the ability of the health and social care sector to deliver more efficient, flexible and higher quality services.

Within this edition you will find an interesting client spotlight on Safar Primary Care and the challenges they have overcome plus a range of articles from lawyers within our Digital Team. This edition sees a focus on the use of data as information governance expert Chris Alderson looks at what you need to know about big data and health technology as well as topical guidance from the ICO around COVID-19.

Also, in this edition, IP and data specialist Matt Donnelly tells you how to protect your IP and sets out some common mistakes organisations can make when dealing with it. I provide guidance on the importance of contracts and ensuring that they are fit for purpose.

After what we hope you will find a range of interesting articles, you will also find details of our core digital team and the services we offer nationwide - we operate across 4 offices nationwide in Harrogate, London, Manchester and Newcastle (although at the moment we are all working from home in lockdown!).

In the past 12 months, Hempsons' notable case studies include advising on a multi-million pound contract for the licensing of an electronic patient record system, the purchase of software by an NHS trust from a global PLC and complex data sharing arrangements between an NHS body and a number of other health sector organisations.

Hempsons' public sector digital expertise is complemented by work for private sector businesses operating in the health and fitness sectors, which has recently included extensive work for our featured client Safar Primary Care and advising a UK based company on the custom development and licensing of their mobile applications to a US based company with operations worldwide.

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Client spotlight...

Safar Primary Care Ltd

Overcoming challenges as a start-up company from an initial idea to launch, how Safar have adapted to an ever-changing world and market place.

In the first of a new series of digital client spotlights, Hempsons caught up with Chris Moore (project manager) at Safar Primary Care Ltd to discuss how Safar has grown as a business and adapted to the challenges it has faced.

Safar Primary Care Ltd has faced several challenges in its short lifetime – but this innovative video-conferencing company set up by two GPs is now planning to launch into new markets.

Safar was the brainchild of Dr Farrukh Shamshad and Dr Saima Qurban four years ago. They could see the need to link patients and clinicians through an easy to use video conferencing system which would allow for an alternative to face-to-face scheduled consultations.

At the time, there were very few companies in this field and some of the products were relatively poor quality or did not offer an appropriate level of security or the functionality required in the healthcare sector.

But the GPs decided they needed help to develop the company and were introduced to Chris Moore, through Hempsons which was already helping them with legal matters. *"We met up and decided we would all get along famously,"* says Mr Moore, who is now project manager at the company. The company then engaged a marketing partner (Beyond) and an IT development specialist (Apacio).

The unique selling point of their product was that it could be used anywhere in the world, he says. *"It could also be used for cross-border prescribing and was very easy for users to access."* GPs would be able to prescribe and the patient then collect from a nearby pharmacy – even if they were in another country at the time.

Europe was identified as a big potential market for the product – but then along came Brexit and suddenly the company's plans were thrown up in the air. Cross-border prescriptions suddenly looked much harder.

But the company was undeterred and concentrated on how a customised product for the NHS could be developed – GP&Me. This is now being piloted among practices in North East Essex and allows scheduled appointments between GP and patient through an app for smartphones and tablets.

The coronavirus crisis has given such technology an enormous boost. Within weeks, many GP practices – and hospital doctors – have turned to virtual consultations to avoid close contact with patients and save them having to come into surgeries or hospitals.

It's probably too early to say whether this shift will be permanent, but many healthcare professionals appear to have adapted well to a different way of working.

Video conferencing is now a crowded market with several big players. *"GP&Me can't really compete with some of these,"* says Mr Moore, *"but it can play its part."*

"We have tried not to be distracted by Covid-19 but we did offer to make it free to anyone who wanted to use it," he says. *"The early signs are good and we are learning as we go. We are already beginning to plan the beta version."*

One of the strengths of the platform is it has been through all the regulatory hoops in the UK – which should stand it in good stead if it is used elsewhere. *"That was good for us because it meant we really had to drill down on data protection. We had to futureproof it and create something simple that could run alongside existing NHS networks,"* says Mr Moore. It also offers excellent audio and video quality, and has a recording facility.

But he says that such advantages don't always last very long and the market is full of companies with deeper pockets. With this in mind, the company is now considering a change in focus. The original Safar idea – of bookable video appointments – will stay centre stage but the company is looking to move into markets in other parts of the world. Nor will it just be confined to its use in health settings. *"We are looking at Asia, as the doctors know India and Pakistan very well, but also the Gulf States,"* says Mr Moore.

Throughout the development of the company, it has worked closely with Hempsons. *"They were absolutely with us along the way. We have worked with a number of colleagues at Hempsons and not one has disappointed,"* he says. *"They know the health sector very well, which is incredibly helpful, but they have also used their own networks and contacts to assist us."*

> ***"Matt Donnelly, our main contact, has been just brilliant. He always does what he says he is going to do and he does it when he says he is going to do it!"***

The often overlooked value of IP and common mistakes in dealing with it.

Do you actually own the content created for you?

We live in an increasingly digital age where technology and innovation are at the forefront of everything we do, with new apps, websites and content being released and published daily, helping us stay in touch with people all around the world.

There is an increasing trend in businesses developing new mobile applications and publishing regular articles and content to promote who they are and the products and services that they offer. However, consideration is often not given to ownership of intellectual property in this content (or 'IP' as it will be referred to throughout this article).

A major error companies often make is failing to realise what IP is and the importance of ensuring that they own any IP created for them. If a company is paying someone to create or build something for them, this does not mean that they will automatically take ownership of what is created. In fact, in the absence of an agreement to the contrary, ownership of the IP will commonly lie with its creator. IP is the term that is used to describe things that can be owned but are not physical in nature; examples of this would include copyright in articles written for publication, the code forming part of an app or even the design behind a logo.

The owner of IP does not own something that is tangible, but instead has the right to control how that intangible thing is used, hence the phrase 'intellectual property rights'. You could have joint ownership of IP - it could belong to individuals as well as organisations and you can also sell and grant rights in IP in a similar way to a tangible object.

It is important for organisations to be aware that IP is a company asset, which in the business world will often carry a significant value in a company's accounts. This is emphasised by figures from a report published by the UK Government, which showed that the world's five most valuable companies, despite being worth £3.5 trillion together have just £172 billion of tangible assets. This means that around 95% of their value is in the form of intangible assets such as IP and data.

It is always therefore essential to ensure that a company owns or has the rights to use the IP that forms part of their app, website or product by considering where the IP comes from and who owns each aspect of it. For example, if a designer created

you a logo, a volunteer wrote an article for your website or a company developed you a new mobile app, then in the absence of an agreement or an employment contract, the IP in those aspects will likely automatically lie with their creator and not necessarily with you or your company. Therefore, you will need the owner of this IP to give the company rights to use the IP that they have created for you.

There are two common ways in which rights can be granted in IP. Firstly, an organisation can be given permanent ownership rights through what is known as an 'IP Assignment', whereby ownership of that IP is 'assigned' to you. Alternatively, where an owner of IP wishes to retain that ownership, then you can be granted the right to use the IP by way of an 'IP Licence'. Licensing is common with photography and you will often see images being licensed by an owner to multiple users through websites such as Getty Images. If you are using someone else's IP that you don't have the rights to use, then the owner will be able to take legal action against you which may leave you financially exposed.

In general, if someone is employed by an organisation then the law states that any IP created during the course of their employment will automatically lie with the employer, unless there is an agreement to the contrary. However, for non-employees such as volunteers or consultants, the IP will typically remain with that individual. You may therefore wish to consider having simple agreements in place with any volunteers or consultants that will enable you to utilise any IP that they create on your behalf.

You should always carefully consider if you have the actual rights to use IP and if not, how you can go about obtaining such rights. If you are developing an app, has the app developer granted you full rights to utilise this as you wish in the future? If you have an image on your website, have you been granted the rights to display it? If a consultant has written an article for you, have they given you the rights to use this online or in print? Of course, if you are unsure on IP ownership or need agreements preparing to give or receive rights in IP, then do not hesitate to give us a call so we can offer you practical legal advice going forward.

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Matt provides advice on a range of commercial issues with his expertise lying in intellectual property, data protection law and commercial contracting. He is a key member of the Hempsons' digital team, helping to drive and enable new technologies and innovations for clients throughout the NHS and the wider health and social care sectors. He has worked closely with global accelerator programs and leading universities to deliver tailored advice to new and scaling businesses on a range of topics including data protection, intellectual property, commercial documentation and corporate structure. Matt also delivers regular advice clinics and training sessions nationwide to leading NHS bodies and innovation hubs on these topics.

Small print for start-ups

This is the best article you will ever read and it will guarantee you success and change your life (terms and conditions apply[1]).

For businesses both big and small it is all too commonplace for contracts to be agreed without either reading or understanding them. For consumers, there are legal protections against unfair terms being imposed on them by businesses. For the most part between commercial organisations there is much more freedom to contract, and much less protection in the event that the terms are unbalanced between the parties. There are, as there often are in law, exceptions to this general rule, but the "basic" position is one of "business buyer beware".

Historically the Courts (and to date Parliament) have considered that largely it is for businesses to sort out their commercial contracts without much need for protection and have left business to business (B2B) arrangements largely unregulated[2]. This may well make sense between two large well-resourced businesses, but the relevant legislation does not differentiate between a multinational business with offices world-wide, and a team of lawyers at HQ, and your new company with only perhaps one or two entrepreneurs as the shareholders and directors. As such, every business needs to know what it is signing up to when it agrees a contract, and it may find itself stuck with the terms, however unfair these are felt to be.

The essential guidance for new business is therefore to read the contracts you are agreeing to be bound by. The law assumes that if you have signed a contract, that you have in fact read it. Except for a very small number of contract types, the law does not require contracts to be signed at all. As the majority of those reading this article will be online businesses, this will, of course, be something of a relief as "signing up" new customers would be much less efficient if this actually involved printing and signing your website terms. Just as consumers can tick boxes to be bound to an agreement, so can businesses.

The term in the small print that has caused repeated annoyance for clients has been the rolling contract term. These automatic contract extension terms are now regulated for consumers, but still commonplace and unregulated in B2B contracts.

These terms provide for the automatic extension of contracts adding a new term at the expiry of the old term. This may be welcomed by a business wanting to keep the contract going with a supplier. However, such a term would be unwelcome where the supplier has not proved to be one that the business would wish to keep using. These clauses can be problematic if ending the new term involves a termination payment for cancelling the contract.

Problems with such a contract term can be mitigated by businesses who are aware of them. Usually such clauses require giving notice at least a specified number of months before the contract is expected to end. Some contracts do not have a maximum period of notice and where there is no maximum, giving notice at the outset of the contract that this will not renew mitigates all risks of automatic renewal. Where a specified period of notice is set, then ensuring that the business has a record of this, and actions any decision to renew or not renew, mitigates the risks of an automatic rolling contract.

As such, our major tip for new (and old) businesses (large and small) is to ensure that you read and understand the B2B contracts you sign up to as you are almost certainly going to be bound to them. With B2B contracts for basic suppliers if you have read and understood the contract, you may rarely need specific legal advice on the terms. Of course, if you do not understand them then you should consider seeking such advice if the contract is of sufficient value or complexity.

1 The terms and conditions are that this may not be the best article you ever actually read, but we thought you might like it. It will not guarantee success, but might help you avoid some pitfalls, and if not actually change your life at least fill a few minutes.

2 The main exception to this concerns where businesses have contracted with the other on their standard terms i.e. without negotiation. In such contracts some (but not all) clauses may be subject to a test of reasonableness.

When reviewing any contract you should, as a minimum, understand the provisions covering:

Parties	Who are the people signing up to the contract? Is the supplier who you expected or some third party? Are you signing up to the business as an individual or for and on behalf of your company?
Is it clear you are getting what you are paying for?	Is the contract clear on what will be supplied by who and when and what the consequences are for delay? Too many specifications are left vague as to what will actually be delivered. We have seen a number of developer contracts that do not expressly assign any intellectual property in the website developed to the paying party- who actually owns the app and website under such a contract should be clear! If the contract is for software - who is a user (to know who in the business can use it). What are the terms for maintenance and support?
Risks?	Is it clear under the contract where all risks sit at all stages of the contract? If you are buying expensive equipment (for example), who bears the risk (and obtains insurance) for the cost of delivery?
Term of contract	How long does the contract last? Can it automatically be extended? Do you understand how this is to be brought to an end, and are any notice provisions clear?
Price and payment	What gets paid and when- and if payment is determined by "milestones" or events, are these clearly set out?
What happens if it all goes wrong?	What are the rights of termination? For example does the contract have a no-fault termination clause to allow earlier than expected termination?
Liability	To what extent are the parties liable for any defaults? Are there any exclusions/caps on liability?
What happens at the end?	Is there any ongoing responsibility regarding confidentiality, provision of information, collection and delivery of records? For example, we have seen large and small businesses hit with large charges if they seek to move stored paper records from one supplier to another if they have not negotiated appropriate clauses covering such uplift events. If the contract is terminated early, are there any accelerated payment provisions or liquidated damages clauses?
GDPR	What terms are in a contract concerning GDPR depends on what the contract is for and what information will be passing from you to the supplier. The terms should reflect whether the supplier is a controller or processor on your behalf. If a supplier is acting as a processor (not controller), the terms must comply with Article 28 of the GDPR.
Jurisdiction and law	Many contracts can be between international parties. You should ensure that you understand what law is applicable to the contract, and which country any dispute would need to be resolved in. Linked to this you should be aware of any arbitration or other dispute resolution clauses.

We will, in future editions of the digital newsbrief be covering tips on agreements between business partners and online contracts and consumer protection- what your contract must say (and should not say!).

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Michael is a corporate commercial solicitor and has broad experience advising a wide range of clients operating across the digital health and broader health and social care sectors. These clients include healthtech and private healthcare companies, charities, GPs and NHS trusts. Michael frequently advises on difficult contracting and regulatory issues.

ICO guidance during **COVID-19**

Like other regulators, the ICO has issued guidance to reassure healthcare bodies and professionals that information governance issues should not be a barrier to effective information sharing to manage the response to the COVID-19 virus.

Outside the mandatory sharing now that COVID-19 has been made a notifiable disease, there will be a need to share information as part of a co-ordinated response. Data protection is often (unjustly) accused of being a barrier to necessary information sharing, but the guidance is a timely reminder that the GDPR is a framework that does not prevent necessary information sharing, and what is necessary and proportionate is context-sensitive: more information may need to be collected and shared in present circumstances than would otherwise have been needed. Likewise, when considering information sharing decisions through the lens of the Caldicott principles and common law confidentiality, the need to protect others from the risk of serious harm will always need to be considered.

The guidance also indicates that the ICO will adopt a realistic approach to compliance with the various statutory deadlines that apply under the information access regimes. The deadlines still apply (they can only be changed through legislation) but when dealing with applicants, and presumably when considering enforcement action, the ICO will be mindful of the fact that healthcare providers will have other calls on their finite resources.

NHSX has also issued its own guidance which complements that of the ICO, emphasising that with changing patterns of working alternative means of communication may be needed, and information governance concerns should not be a barrier to necessary information sharing or the use of alternative methods of communication, such as video conferencing and instant messaging.

While this pragmatic guidance is to be welcomed, it does not mean that ordinary information governance measures should be disregarded. The normal safeguards for protecting data will still need to be observed, even if these are applied in a new context, and the ICO's pragmatic stance does not mean compliance can be ignored, especially in cases where in fact the steps needed are unaffected by the pressures on the organisation.

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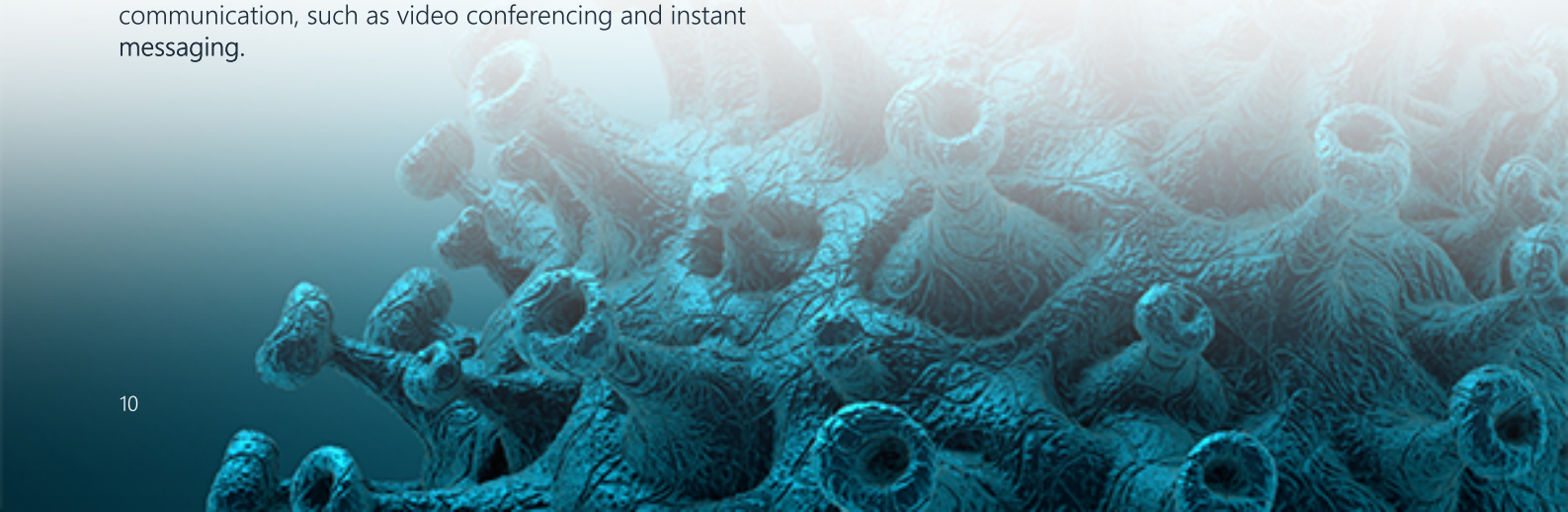
Chris is a leading information lawyer and advises a wide range of local, national and international health and third sector organisations on information law and legal and practical aspects of the data protection and freedom of information legislation. Chris has expertise in the particular ethical rules governing the use of health data, and especially in the developing area of using information derived from health records with AI techniques to discover improved treatments. He has advised the NHS on a lead Test Bed project involving a major pharmaceutical company, and also advises digital health companies developing such products.



Fit for purpose?
What the NHS needs to know about big data and health technology

Key points:

- **Steps are now being taken centrally to adopt a co-ordinated approach to using NHS data and new technologies to unlock improvements in health care.**
- **Guidance is still high level, but more detailed work is expected.**
- **A strong legal and ethical framework will form the core of these requirements.**
- **The commercial value of the data should not be underestimated – particularly bearing in mind the investment in NHS infrastructure that has made such projects feasible.**

As technology and innovation take an increasingly key role in the ability of the health and social care sector to deliver more efficient, flexible and higher quality services, we have seen 'Big Data' and machine learning-driven AI projects using NHS data, climb up the political agenda, as both the potential for healthcare improvement and the value of such projects have become more widely known and understood. In this article we take a look at the developments in this area and the changes we are likely to see in the future.

As anyone with more than a passing interest in the secondary uses of health data will be aware, there is an initially baffling number of official sources of advice and guidance on the information governance issues relevant to its use with new technologies. The fragmented nature of this guidance was exemplified by media coverage of a 'new' ban on exclusive data sharing arrangements in the NHS introduced in July 2019, despite this already being existing government policy. (Admittedly it was tucked away at page 46 of the December 2018 *'Industrial Strategy – Life Sciences Sector Deal 2'*!)

It is therefore not surprising that there is a lack of a common understanding of the principles to be applied, even within the NHS economy. These problems are magnified when dealing with the big tech, data and pharma companies who are not used to working with NHS data in this way and have little institutional experience or knowledge of the limitations on using patient data for purposes outside direct care. This can result in unintended consequences, such as those arising out of the Royal Free/Deep Mind "Streams" project.[1]

Everybody involved needs central, authoritative and accessible guidance to be produced. Thankfully some steps in this respect are being taken.

In July 2019, there was a flurry of activity from the Department of Health and Social Care which sets out a road map of how such data projects are likely to be governed in the future. As well as updating its Code of Conduct for Data Driven and Health and Care Technology, the DHSC published the guidance "Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation". This outlines the plans for NHSX to take the lead on strategy and guidance in this area. Five guiding principles for NHS data projects are outlined.

In summary, these are:

1 Any use of NHS data must have the explicit aim to improve the health welfare and/or care of NHS patients, or improve the operation of the NHS.

2 The importance of NHS data as a resource must be reflected in ensuring fair terms for the use of NHS data for their own organisation and the NHS as a whole.

3 The arrangements should not inhibit or restrict the ability of the NHS as a whole, including a reiteration on the prohibition on exclusive data access deals.

4 Public trust is vital, so transparency and communication are necessary.

5 All existing national, legal, regulatory, privacy and security obligations should be met, including the National Data Guardian's standards.

The guidance also outlines plans for NHSX to set up a National Centre for Expertise for data agreements and projects, publishing guidance, standards and templates. Such work will undoubtedly be invaluable, but at present much of the published information is a high-level indication of future projects rather than

[1] See, for example ICO press release 31 July 2019

direct practical solutions, and in relation to these data projects the devil is very much in the detail.

There is an increasing understanding of the value of NHS data in purely commercial terms as shown, for example, in the report by EY on 'Realising the value of health care data: a framework for the future'. A direct translation from commercial database sales to NHS data is not possible, as the protections for NHS data will mean that there will always have to be some purpose limitation and controls over data shared. Even within such constraints the commercial value of NHS data is potentially immense, with the ability to provide linkages between primary and secondary care over a lifetime, and at a scale and population diversity not currently replicable anywhere else in the world.

The datasets analysed in traditional assessments of efficacy and cost effective of pharmaceuticals and treatments will often be tiny in comparison to the information potentially available from NHS data, so there is a clear imperative for commissioners, suppliers and providers to work together to utilise the best evidence available.

Whether and how that value should be realised raises complex ethical and practical questions. For many the idea of commercial exploitation of NHS data will be redolent of selling patient data for profit or might be seen as impeding medical research. However, just as is the case with the pharmaceutical industry, progress may only realistically be possible within a commercial environment. With appropriate safeguards the benefits of interrogating mass de-identified data bases can be realised while still maintaining the core NHS principle of protecting individual privacy.

While making data available without charge may seem more in line with the spirit of the NHS, it is worth bearing in mind that this incredibly fruitful information source is only available to be analysed as a result of billions of pounds of investment of public funds. This may provide reassurance that there is a strong moral case that it is only fair and just that the NHS seeks a return on this investment, particularly when the data is used in commercial projects.

There may be lessons to be applied from the purchasing of medicines. Even the president of the United States is aware the NHS is able to secure a better deal from its medicines suppliers by bargaining on behalf of the NHS as a whole. Likewise, central negotiations for commercial data deals will result in better overall value for the NHS than individual local bespoke agreements.

We are still very much in the early days of what has the promise to revolutionise healthcare. However, there are clear indicators of how future guidance is likely to be shaped and so those responsible for planning Big Data projects should bear in mind the following points:

- Health data should not be commoditised – it should not and cannot simply be sold.
- Ensure there is a proper ethical and legal framework applied to the use of even de-identified data.
- Be transparent about who is working with your data and how it is being used. If the potential users of data are unknown, you need to have clear and transparent idea of types of user and types of project that will be involved.
- Regulation of this area is likely to be tightened in the future, so what is currently good practice is likely to be mandatory as time goes on. Similarly, previous projects may not necessarily meet current standards and so may have limited precedent value.

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Our services

Setting up your business and corporate structure
Selecting the right entity (company, LLP, CIC), company incorporation, shareholders and partnership agreements and related advice.

Regulatory compliance
Guiding you through the alphabet soup of health regulators - CQC (HIW in Wales), GDC, GMC, GPhC, HCPC, HFEA, HSE, MHRA, NHSX, NHS Digital, NMC & etc.

Data protection
GDPR & DPA compliance including drafting privacy/transparency notices, advice on data registries and cloud computing, international data transfers, AI/machine learning, access to health data held by public bodies and clinical research projects.

Information governance
ICO regulatory compliance, NHS information governance rules and Freedom of Information (FOI).

Apps and software
App development agreements and End User Licenses (EULA), Software as a Service agreements (SaaS), medical device regulation (can be applicable for software) and accessing the NHS apps library.

Medical devices and in vitro diagnostics
Compliance with MHRA requirements, CE marking requirements and advice on MDR and IVDR.

Intellectual Property
Protecting what's yours through non-disclosure agreements (NDAs), trade mark applications, design registrations, copyright and other IP such as licensing and assignments.

Marketing and Ethics
Lawful use of email databases for marketing (PECR) and advice on ethical/regulatory restrictions on advertising in the health sector.

Contracting with consumers and patients (B2C)
Helping you prepare terms and conditions with your customers, compliant with Distance Selling Regulations and consumer rights law.

Contracting with third parties (B2B)
Preparing commercial terms and contracts for you to use with your suppliers and business customers.

Pre-seed, seed and series A investments
Helping to protect your interests when raising funds for your business from investors.

Employment
Providing advice on employee contracts, subcontracting and freelancer arrangements, directors service contracts and all things 'staff' related.

Selling to public bodies
Engaging with the NHS and public sector frameworks and advice on procurement regulations.

Property and premises
Establishing clinics and advice on leases, licences and tenancies.

Disputes
Should things go wrong with customers, partners or suppliers, our experienced dispute resolution team can guide you through mediation, arbitration and litigation.

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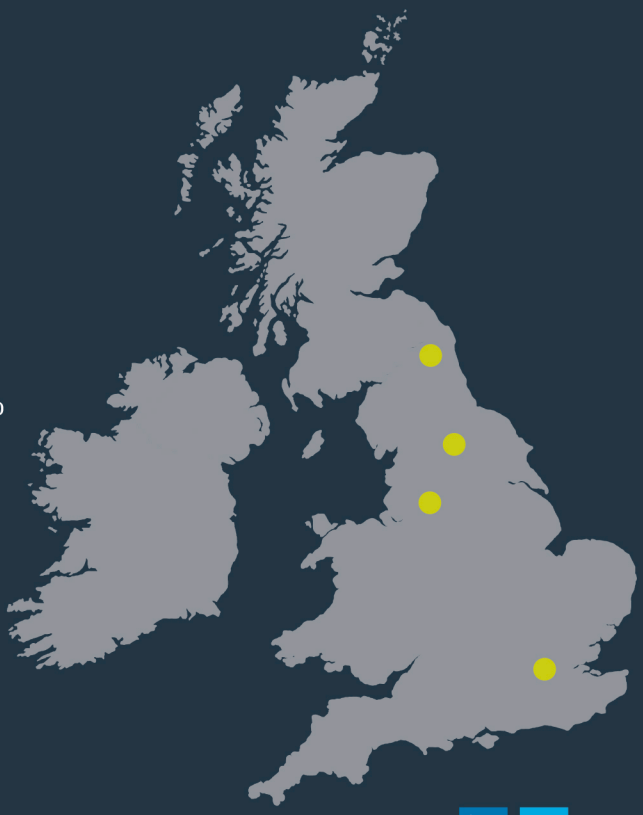
HEMPSONS

Please email digital@hempsons.co.uk for more information or assistance with any legal issues you are facing

About Hempsons

Hempsons is a leading national law firm specialising in health and social care law, across the UK. Our highly experienced lawyers provide cost-effective solutions for a range of practitioners and private and public healthcare organisations, from employment law through to clinical negligence.

We aim to achieve our clients' objectives and provide support down to the last detail whether the issue is big or small, challenging or simple. A significant number of our employees hold dual qualifications, combining medical, dental or nursing qualifications with their legal credentials.



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