

WELCOME TO FUTURE MEDICAL SYSTEMS!

THE QUICKSTART GUIDE

We are excited and delighted that we are on the path to work together! Between now and the kick-off is an opportunity to lay plans that will get our shared project moving more quickly and more smoothly.

Over the years, we've learned that there are several additional steps between accepting the proposal and kicking-off where there may be surprises and hurdles. We've compiled this 'Quickstart Guide' to share with you what we've learned. It's unlikely that all of them will apply to this project, but hopefully we can avoid a few road-bumps together.



AVAILABILITY AND SCHEDULING YOUR TEAM

- Are all the participants in this project in your organization aware of their roles and expected level of commitment? Might they need help explaining their role to their line-manager? We can help by providing a short project summary if required.
- Can we start scheduling the most senior project stakeholders for a tentative kick-off date? (sometimes they schedule 4+ weeks ahead of time).



FMS TRAINING & SCREENING

- If your organizational policies require consultants to complete any training (e.g. pharmacovigilance, research processes, professional ethics, data security, informed consent) please let us know as soon as possible.
- Please let us know if our team is required to conduct medical screenings (e.g. TB) or drug tests and consider starting the process early.



CONTRACTING

- **Contracting can take longer than expected** and can't be predicted exactly. FMS is committed to being flexible so we promise to move quickly on our revisions and

keep you updated on progress. Typical timelines in our experience are 2 to 6 weeks or more. Although our business relies on us reaching an agreement, sadly there are times when differences cannot be resolved.

- **Our strategic design services can be unfamiliar to our client's legal representatives:** For contractual purposes, our services fit best into a 'Consulting Services' agreement, if your organization has one. Typical Services Agreement (MSA) templates are written with vendors that deliver a specific 'thing' that is provided ready for use (e.g.. hardware, marketing materials, software installations) in mind. That is not the nature of our work: we are consultants delivering a process of innovation and we guarantee the quality of that process.

Most importantly, the final implementation of the ideas that we work on together will be created by your team, so FMS cannot assume liabilities for something that we will not be creating. If you can explain this to your legal team it will accelerate negotiations.

- **BAAs:** Our US clients typically need FMS to review and sign a Business Associate Agreement. If this is the case, please supply this at the earliest opportunity. We are familiar with this process but every BAA is different and we will need to review yours and address any unique needs that you have.
- **The Deposit Payment:** Our terms of business require that a first payment (an agreed percentage of the total) is deposited to us before the project kick-off. This is because we will immediately start activities such as recruiting that require us to incur expenses. Please coordinate with your accounts payable group to determine how long this first payment will take to deposit. Sometimes the process of triggering a purchase order is different to just a signed proposal.



RESEARCH AND RECRUITING PROCESSES

To go into the field, we will need both a process for contacting and selecting participants, and a set of legal documents for the participant to sign. Your organization's past experience and policy will determine how we do this together.

- **Policy:** Some companies have policies that limit how staff and contractors contact and interact with the people we will be speaking to (clinicians, patients or potential customers). Please share these with us at the earliest possibility
- **Data security/PHI:** Gathering names and addresses is usually covered (in the US) by federal law (HIPAA). We—and our subcontractors—are trained and practiced in these requirements and have processes for handling this data. If we will be sharing this information to you we will need to determine a process to ensure data security. We are happy to start discussing this today!
- **Honoraria/Participant Compensation:** It is typical and highly recommended to compensate all research participants for their time. The expense estimate of the project already covers participant compensations. However, different companies have different policies that may affect how (and if) we can pay participants. You can choose:
 - To have us compensate participants directly and then expense the amount to your organization
 - To directly pay participants from your organization—clients sometimes prefer to use pre-paid credit cards for this

Either option is acceptable to us, but it is worthwhile finding out what is preferred/allowed in your organization.

- **Participant documents:** Together, we will need to agree to a set of legal documents for participants to sign. This typically includes:
 - Informed consent to take part in research
 - A liability waiver for the participant's involvement
 - An NDA to not reveal the contents of the interview
 - A confidentiality guarantee that we will not share their information publicly
 - Permission to share what is learned within your organization, including photographs or other media
 - A receipt for the compensation

FMS has template documents that include all of the above, but it is often the case that your organization's legal team will have a point of view on the contents, and may require modifications, or a custom set of documents. Defining this process can be time-consuming if your legal team has not done this before. Please provide any past examples that you have used, or ask for our templates.

These issues can become daunting, but Future Medical Systems will always try to go the extra mile to accommodate your specific organizational needs. Please let us know if you'd like to understand any of these issues in more detail. Ultimately, we are here to build a team with you and have a successful project together.