Geographies:

- Western Europe (UK, Spain, Ireland, Germany, Austria, Belgium, Netherlands, Italy, Denmark, Switzerland, Greece)
- Asia including Japan (S Korea, Taiwan, China, Singapore, Hong Kong, India, Australia, Japan)
- North America (Canada, US, Mexico)
- South America (Brazil, Argentina)
- Africa (Zimbabwe, Uganda, South Africa)
- Middle East / Eastern Europe (Poland, Czech Rep, Slovakia, Hungary, Croatia, Turkey)

Questionnaire

Common Sponsor Areas of interest	MB answer	What we define
Indication Focus Areas	• All Solid Tumors • Blood Cancers (All Hematological Malignancies) • Rare Disease related to Hematology and Oncology • Stage I-IV	TAs in which we specialize and where we are emerging.
Indication Focus Areas Notes	Beyond the TA mentioned above, we have most success in: • Biomarker-based oncology trials (IHC,FISH, NGS, RNA, liquid and tissue assays) • Highly competitive landscape • Difficult to enroll populations • Diversity and Inclusion needs • Concierge Enrollment Needs • Just-in-Time and Decentralized Trials • Requirement of academic-community referral network referral optimization	Expansion on our TAs and areas in which we have been particularly effective or a novel approach was developed.
Geographic focus	We have presence and full operations in US, Brazil, Canada, France, Germany, Greece, Israel, Italy, Poland, Romania, Spain and Turkey. MB patient advocates native speakers in each country for context and cultural appropriateness. Emerging: Argentina, Colombia, Singapore, Japan, Taiwan, Australia.	In what countries does our platform and business model have a positive track record and experience. Where is it emerging? Specific expertise and cultural competencies.
Geographic focus (regulatory comments)	We have the following compliance assurances: • The SYNERGY-AI Clinical Trial Matching System platform was developed with human subject protection and data security as a top	Where do we have experience from a regulatory perspective? Working w health authorities, GDPR, etc.

	priority, and no breaches or serious security concerns are associated with deployments released to date. In terms of US regulations that Massive Bio follows:
	• In the US, Health Insurance Portability and Accountability Act of 1996 (HIPAA) and FDA guidelines are the most relevant regulation for its services
	  ○ Federalwide Assurance (FWA), FADP, EDPB, FDA compliant approach
	  ○ SOC 2 certified
	  ○ Our privacy policy is on our website: https://massivebio.com/privacy-policy
	  ○ In addition, we have obtained the following certifications for quality, patient protection, and privacy assurance:
	  ○ To be compliant beyond HIPAA in the context of clinical research, the Office for Human Research Protections (OHRP) has approved Massive Bio's Federal wide Assurance (FWA).
	  ○ Massive Bio submitted all the documentation OHRP requires to constitute a commitment by the institution to comply with the requirements of 45 CFR part 46 when its employees or agents engage in non-exempt human subjects' research conducted or supported by HHS or other research covered by the assurance.
	  ○ The Federal wide Assurance is the only type of assurance accepted and approved by OHRP. This can be verified at https://ohrp.cit.nih.gov/search/FwaDtl.aspx . Massive Bio's ID is FWA00030601.
	• In terms of Europe, Israel, Brazil and other country regulations that Massive Bio follows:
	  ○ In European countries and the UK, GDPR https://gdpr-info.eu/ and Clinical Trials Regulation (CTR - Regulation (EU) No 536/2014)	

	https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation compliance are the most relevant regulation for its services ○ Germany: German Unfair Competition Act (Gesetz gegen den unlauteren Wettbewerb – “UWG”), and the German Drug Advertising Act (Heilmittelwerbegesetz - “HWG”) ○ France: Article L.1121-1 of the French Public Health Code (“FPHC”) and EU Good Clinical Practices which are integrated in French law by a “Décision du 24 novembre 2006 fixant les règles bonnes pratiques cliniques pour les recherches biomédicales portant sur des médicaments à usage humain “published in the Official Gazette on November 30, 2006 (the “ANSM GCP”) ○ Greece: Ministerial Decision 59676/2016. ○ Italy: Ministry of Health, the Superior Institute of Health (“Istituto Superiore di Sanità”) or the Italian Drug Agency (“Agenzia Italiana del Farmaco”) as provided by Article 2, paragraph 1, letter t) of the relevant Decree read in conjunction with Decree No. 158/2012 (which transferred most of the competences regarding the authorization for clinical trials previously attributed to the Superior Institute of Health to the Italian Drug Agency), Article 6, paragraph 2 of Legislative Decree No. 211/2003, and Article 19 of Legislative Decree No. 211/2003. ○ Poland: Polish clinical trials registration authority (President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) ○ Romania: Order of the Minister of Health no. 904/2006, and National Agency for Medicines and Medical Devices of Romania (“ANMDM”)	

	regulations.Emergency Ordinance no. 29/2022 on the establishment of the institutional framework and the measures necessary for the implementation of Regulation (EU) no. Regulation (EC) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on interventional clinical trials with medicinal products for human use and repealing Directive 2001/20 / EC ○ Spain: Spanish Royal Decree 1090/2015. ○ We are compliant also in Turkey (MoH), Brazil, Colombia (Invima) and Israel Public Health Regulations (Clinical Trials in Humans) 1980 (the "Regulations") and Ministry of Health ("MOH") Clinical Trials Procedure No. 14 (2020) (the "MOH Procedure") ○ EDPB compliant approach ○ Privacy Shield Certification • In addition, we have obtained the following certifications for quality, patient protection, and privacy assurance: ○ All key Massive Bio team members are trained and certified in Good Clinical Practice (GCP), covering International Council for Harmonisation (ICH) E6 Good Clinical Practice (GCP) guideline essential topics for clinical trials with drugs and biologics. It describes the responsibilities and expectations for the conduct, monitoring, reporting, and documenting of clinical trials. It is intended for research personnel involved in drug and biologic studies and who would benefit from a more internationally focused training, or for researchers involved in studies where compliance with ICH is required (for example, most industry-funded studies). It should be noted, however, that when appropriate, references to U.S. Food and Drug Administration	

	(FDA) regulations and guidance are included. ○ The course covers key topics in clinical research including: • Reviewing ICH GCP standards • ii. Reviewing FDA regulations • iii. Identifying investigator and sponsor obligations • iv. Discussing new drug development • v. Comparing ICH GCP E6 guideline and FDA regulations • vi. Describing how to detect and report adverse events • vii. Auditing and monitoring expectations • viii. The Collaborative Institutional Training Initiative (CITI Program) is dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners.	
Language capability	We have local native speakers in US, Brazil, Canada, France, Germany, Greece, Israel, Italy, Poland, Romania, Spain and Turkey. We have full translation capabilities through external vendors (e.g. Transcarent) and confirmed by our MB patient advocates in each country for context and cultural appropriateness.	What languages do we operate in? Which ones are we expanding into? Overall translation capabilities, if we employ native speakers, etc..
Business model (pay4performance, blended risk, etc.)	• Blended risk (most common model) • Pay for services (only for Site Selection and Optimization Services)	Definitions: • Pay for performance – sponsor only pays when specific success benchmarks are met (IE – randomizations, IFC sign-ups, screen pass) • Blended risk – sponsor pays some fees, but vendor randomizations or other performance goals are in play • Pay for services – sponsor pays a standard fee schedule for all services, regardless of referral success • Other pricing approach – pick this if you definitively do not fit into the other options and explain in the “business model details” section.

Business model details	Comprehensive, 100% transparent fee structure, no extra or hidden costs. While we have a blended risk model, two-thirds of the contracts involve a pay for performance component. Blended risk (most common model) includes: • Pay for performance – sponsor only pays when success benchmarks are met (in most cases randomization and first dose-in) • Pay for services rendered: Trial Startup (1 time), Site Selection and Optimization Services (1 time), and Monthly Project Management Services. There will be no monthly project management fees after 12 months regardless of recruitment timelines past 12 months. • Customizable to US and OUS • No additional cost for 5+ countries if engagement is over 6 months for OUS. Moreover, many of our clients have a three tier Model: • Single engagement equals 1 trial • Program level engagement equals multiple trials because we are asked to cover a “program” such as breast cancer program or lung cancer program • Portfolio/Pipeline engagement equals Sponsor’s all oncology/hematology pipeline and we match the entire pipeline to our entire patient population and the client signs an annual license with us similar to some of your “traditional” data vendors	
Patient referral methods (ads, database, etc.)	• Advertising for specific cancer types and biomarkers. Advertisement for specific trials is not usually successful in our experience. • Database building against TAs • EMR scans against protocols • Integrations with medical and academic centers	

	• Community site partnerships for patient referral • Partnerships with advocacy groups • Direct relationships with a network of sites (traditional, decentralized, and JIT site selection) • **Other:** • <u>Direct to Patient:</u> • Provider Call Center Referral • SEO and Content Generation, landing pages • Online and Offline Community formation • SYNERGY-AI Mobile Application • Oncology Nurse Hour • Patient Ambassador Program • <u>Indirect to Patient:</u> • Online Provider Referral Program • Virtual Tumor Board Referrals • Community Oncology Advisory Board • NGS Vendor Referral • Payer Prior Authorization Referral • Specialty Pharmacy Referral	
Referral method details	**Patients On-boarded from Our Patient Contact Center:** <u>Provider Call Center Referral Activation</u>: We notify our provider partners about the Sponsor study, specific biomarkers, and disease stage types, and we get referrals to our patient contact center from their patient contact center. <u>Online Marketing Channel Activation</u>: We develop Sponsor study, specific biomarkers and disease stage types of Facebook and Google ads targeting locations around Sponsor sites. We further develop biomarker-specific and disease-specific landing pages, micro-sites, and configure Massive Bio's direct to patient mobile applications with such content. <u>Social Media Group Activation</u>: We develop Facebook groups focusing on specific	Details about our referral methods. Is there anything you feel is unique or different about our model?

	biomarkers and disease stage types, (the group will not be linked to Massive Bio) which will be utilized to bring in and engage disease specific and/or biomarker-driven unique patients. We develop focused education on each biomarker and variant(s) as needed, and flexible if protocol has a seamless design to allow combination and expansion cohorts. Massive Bio will also share related biomarker-specific and disease-specific information on LinkedIn, Facebook, Twitter, and Pinterest daily. Mobile patient engagement with SYNERGY AI and Cancer Quiz App Oncology Nurse Hour: We ran oncology nurse hours as well as virtual pre-screening events to educate patients and potentially community physicians on the importance of clinical trial participation. Previous Clinical Trials based events can be found in the following links: ● https://www.youtube.com/watch?v=NaYURbdtGfU ● https://www.facebook.com/watch/?v=155737056651357 ● https://massivebio.com/biomarker-clinical-trials-ultimate-guide/ Patient Ambassador Program: In this program, we foster a community of cancer patients at all points in their journeys to give patients a voice and a platform to share their experiences and connect with others. This patient community is a safe space for patients to share their stories, their fears, and their hopes with others in similar situations. Watch a patient story, https://massivebio.com/patient-ambassador-program. Patient Advocacy Group Activation: We need to maximize patient referrals from patient advocacy groups. We will work with patient advocacy programs directly to identify and	

	pre-screen appropriate patients. However, it is important to understand that biomarker specific patient advocacy groups are limited and thus we typically create our own communities though it takes time to build ground up. **Patients On-boarded from Provider Partners:** Referral Network Activation: We identify referral network sites within 50 miles (or any mileage of Sponsor's preference) of each Sponsor site, we educate the referral sites about the study and conduct high-level feasibility if the referral site has enough patients to refer to the Sponsor site. We typically identify couple of hundred referrals sites and then prioritize close to 50 VIP sites for continuous daily engagement after initial reach-out to the site(s). Based on our analysis, it has been consistently shown that referrals sites typically have no knowledge of a study nearby, especially for those studies with limited patient volumes, given that they do not have options in their practices, it is crucial to provide right education and awareness. Provider Network Activation (incremental to Referral Network): Incremental to referral sites, we are currently working with 1500+ sites to review patients for our Sponsored studies, 75 sites we are working more than one study. We also leverage those sites to further expand provider network reach-outs. In addition to traditional provider-based referrals, we get patients from payer's prior authorization units and specialty pharmacies which provides us an expanded access to large number of patients at the right time. We leverage Massive Bio's relationship of enrolling in NCI sponsored trials and NRG to identify non overlapping sites across the NCTN research network. It is important to note that Massive Bio is NCI's official vendor for "Cancer Clinical Trials Recruitment and	

	Retention Tools for Participant Engagement" in NCI-supported clinical trials. We leverage patients searching and/or participating in clinical trials and real-time patient activation, from existing and non-contracted clinical trials, using Massive Bio's SYNERGY-AI registry (https://clinicaltrials.gov/ct2/show/NCT03452774). Massive Bio is the first organization that has established AI based registry for biomarker-based studies. Criteria as defined in Sponsor already part of existing machine learning matching algorithms in SYNERGY-AI leveraged within Massive Bio's Deep Learning Clinical Trial Matching System (DLCTMS). Unlike other vendors, we have established relationships with NCI-MATCH affiliated, RTOG, and NCTN Oncology Group sites, which allows Massive Bio to identify potentially eligible patients before and after NGS and/or systemic therapies, which is a crucial task for the performance of many trials. We review J codes, Q codes, CPT codes for genomic testing, ICD 10 codes and our patient access channels combination for highest yield population and assess sites for Just-In-Time (JIT) activation there – Allowing patients to remain at same site where they have received treatment, if they have the research capabilities so JIT is best approach. This approach is optional based on Roche's desire to utilize JIT along with traditional sites. We have capabilities to engage patients to participate in master biomarker and/or pre-qualifying screening studies. The overarching structure of those studies is a flexible master screening process where tumor tissue from eligible patients will be submitted for centralized, indication-appropriate biomarker testing, as needed for linked trials, including validated	

	molecular testing and immunohistochemistry assays, as required according to the disease indication and staging. Results of biomarker testing will be used to determine biomarker eligibility of patients, and where applicable, for stratification purposes required for participation in a linked Sponsor clinical trial. We are the experts in NGS workflow, ordering and closing the education and operational gaps after results are obtained from NGS providers which can generate significant value to the trial. Our dedicated oncology nurses and advocates are educated to facilitate ordering and completion of comprehensive genomic testing documentation, as needed, based on the list of CLIA-certified laboratories per protocol, including Foundation Medicine. This further increase patient's motivation to get tested and potentially be eligible for the study. Our case management team is typically on the phone with Academic in-house NGS panel providers, Foundation Medicine, Guardant Health, NeoGenomics, and CARIS daily. If NGS Vendor and/or Sponsor flags a patient to Massive Bio, we can pre-screen the patient with Massive Bio's DLCTMS and issue a report to be used for JIT activation or site referral. This also improves awareness of trials and understanding of reported novel biomarkers which may be helpful to the patient. Unfortunately, majority of the patients will not be at the Sponsor sites and without the concierge enrollment services of Massive Bio to refer these patients (e.g. scheduling a meeting between treating oncologist and PI, insurance review, transportation coordination, patient engagement tools/services, etc.) to Sponsor sites, we have consistently have seen that	

	treating providers ability to refer those patients is close to zero. We have payer partners where we work with their prior authorization units to identify patient population of interest and notify the provider for referral interest.	
How do you pre-screen or qualify patients?	**Direct to patient** • Massive Bio advertises its clinical trial search engine and education about clinical trials in several disease types and biomarkers through search engines, social media, and through referrals from stakeholders in cancer care seeking help in finding and navigating clinical trial search. • The patient contacts the Company by phone/email/website. The Company`s local patient advocate contacts the patient and advises him/her in regard to the services. • During this, the local patient advocate conducts an initial qualification of the patient for clinical trial matching in terms of cancer diagnosis, ability to understand the language and the willingness to sign a consent form to review medical records submitted by the patient. • Once the patient has passed the basic qualification, the patient signs the Company`s consent form ("Synergy AI HIPPA/GDPR Release and Informed Consent Forms": "Health insurance portability and accountability act (HIPAA) and non-US countries general data protection regulation (GDPR) consent and release form" and "Research subject informed consent form"). • Based on this consent form, the local patient advocate collects medical records from the patient and/or his/her doctor. • The collected records are then de-identified, classified, translated into English (if required) and structured in parameters to check all data for accuracy and timeliness. • The Company`s supervised AI technology pre-screens the patient to any cancer clinical trial that is actively recruiting at ClinicalTrials.Gov.	Sending qualified patients to a site is much more critical than quantity. Here we explain how we vet patients before sending over. Do we have a call center or any type of human vetting process? Do we utilize AI or machine learning?

	• The necessary inclusion and exclusion criteria for the specific study are obtained from publicly available sources or provided by the respective study sponsors.
	• The results of the prescreening are communicated to the patient by the oncology research nurses and local patient advocates.
	• The results include the clinical studies the patient may be eligible for, rationale, prioritized by location, cancer type and biomarker.
	• The information provided to the patient is limited to general information regarding the individual studies recommended to him/her. Any influence on the decision-making process is avoided.
	• Massive Bio educates the patient and primary oncologist about the trial options, and once a decision has been made, Massive Bio facilitates first screening visit.
	  ○ Confirms trial status at site and insurance eligibility
	  ○ Forwards any required medical records after we facilitate HIPAA/GDPR consent form by the patient
	• Massive Bio resolves 'last mile' logistical and financial issues of the patient to ease referral process and increase patient's ability to stay in the patient's preferred and referred study during the enrollment period.
	
	<u>Indirect to patient (activated mostly in OUS)</u>
	
	• The Company identifies the local oncologist/primary physician/specialist that can potentially have the relevant patient population for the study; this identification is done by outside in due diligence (i.e., publicly available information).
	• The Company sends local speaking provider engagement team member to medical practices / hospitals across the country to seek patients and raise awareness on clinical trials.
	• The Company has no insider information about these physicians/hospitals. Especially there are	

	no agreements or collusive arrangements with these physicians and/or hospitals. • The treating physicians are to select suitable patients for studies, whereby the Company does not at any point receive any patient data or identifiable information • The Company´s engagement team discusses with the physician the studies to be considered and/or the respective requirements that the patient must meet. The information provided to the physicians is limited to general information regarding the individual studies recommended to him/her. Any influence on the decision-making process is avoided. • Once the patient is identified, the treating/referring oncologist refers the patient to the Sponsor site (more specifically Sponsor PI at the site) after discussion with the patient. • The Company´s engagement team member continuously follows up with the referring oncologist when patient is not ready for enrollment but partially eligible for the trial. • If the patient is interested, the attending physician asks the Company to contact the patient in question. The further procedure is similar as if the patient contacted the Company directly.	
Diversity focus	Massive Bio has customized its site selection and patient enrollment products to focus on diversity, equity and inclusion (DE&I) initiatives for both compliance obligations and to increase the overall participation of more diverse, equitable and inclusive population in clinical trials. Philosophically, the company was founded precisely for that purpose of equity, and its co-founders include such diverse members. Massive Bio has a framework based on FDA's "Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry". Underrepresented Population Enrollment: To ensure diversity in the enrollment, particularly in the US,	Here we describe our focus in diversity - both philosophically and operational. How do we actually make it happen?

	Massive Bio dedicates at least 15% of patient enrollment effort to diverse patients, including African American and Hispanic populations. • Community oncology focus and outreach • Data driven patient targeting/hot spot population analysis and targeting based on race, ethnicity, etc. • Development of culturally concordant content • Our ontologies, data management and algorithms include social determinants of health to reduce biases and promote diversity in clinical trial screening and enrollment. • Multi-language content in all media, websites, mobile Apps, and case management Massive Bio is the only oncology specialized patient enrollment company in the market integrating social determinants of health to optimize any project and maximize diversity plan deployment. Massive Bio was selected as unique vendor by the National Cancer Institute for Cancer Clinical Trials Recruitment and Retention Tools for Participant Engagement (Small Business Innovation Research (SBIR) Contract No. 75N91020C00016) which focuses in improving access to clinical trials for underrepresented patients in the US We customize our approaches based on the specific clinical trial's needs in terms of diversity and inclusion, aiming to FDA suggested goals, and the deployment of the specific strategy proposed by sponsor. We support sponsors at all phases of the development of such plans. Typically Developing a DE&I initiative and Trial Specific Diversity Plans involve four main phases, all part of initial due diligence and ongoing project management: • Data collection and analysis to determine the need for optimization of underrepresented population.	

	• Strategy design to match trial and regulatory-related objectives. • Implementation of the initiative over the anticipated timeline. • Evaluation and continuing audit of the plan to drive success – Project management.	
Retrieving Patient referrals	All our Massive Bio services were developed to facilitate the identification, tracking, referral and tracking easier for all stakeholders, reducing burden and delays. Patients get concierge level enrollment, which implies optimal experience (please review our 5 star Google reviews at your convenience) <u>Sponsor:</u> See Startup Process below. <u>Sites</u> **1. What Massive Bio will do for sites:** • Identify potential patients through a HIPAA/GDPR-compliant consent process, and once records are obtained, will pre-screen medical records including NGS and biomarkers (if applicable) to qualify fully eligible patients, and then refer to closest active site, • Educate the patient and primary oncologist about the trial to facilitate first screening visit, • Resolve last mile logistical and financial issues of the patient to ease referral process and increase patient's ability to stay in the referred study during the enrollment period, • Facilitate physician to physician transfer – enable streamlined referral between patient's primary oncologist and the sites, • Allocate a dedicated, advanced trained Case Manager Research Nurse, who will support site and busy staff in tracking referrals and removing barriers to screening visit and ICF discussion. **2. What is Massive Bio's value proposition to site?**	• Steps **sites** must take to retrieve referrals, track them, etc. • Steps or tasks a **sponsor** will need to do in order operationalize your platform (especially ongoing steps) • Any **patient** potential experience burden interacting with your services

	• There is no cost to you or the patient for patient referrals, • There is no need to merge technologies for referred patients. Your standard site systems/processes will be followed, • Your staff burden will be reduced. **3. What happens after site gets a Massive Bio referral?** Massive Bio's dedicated case managers will contact key personnel at site, and will be available to discuss logistics for the referral, including: • Confirm trial status at site and insurance eligibility • Forward any required medical records after we facilitate HIPAA consent form by the patient • Resolve any financial assistance issues and travel logistics as needed • Schedule first appointment at enrollment site • Continue supporting the patient and helping the patient to work collaboratively with the site	
Startup process	• Enrollment efforts will start immediately following site activation and SOW signature • There will be a due diligence process of 6-8 weeks for referral network, site and PI analysis which is aimed to accelerate enrollment further. • Meetings with key trial managers at the Sponsor's required cadence (usually every 2-4 weeks). • Country-level and site activation.	What are the steps in bullet points to starting up a referral program? This described a mini-project plan that shows contract to implementation in weeks.
How will we measure success?	Massive Bio provides monthly patient funnel report for the Sponsor to optimize its patient recruitment strategy. The patient funnel report typically includes the following 10 items; however, in the case that the Sponsor would request any additional report/information about the patient funnel, Massive Bio will not charge any additional fees and provides	We mention about how a sponsor can determine the effectiveness of our efforts and attribute randomizations and referrals to our services. How do sponsors justify using us repeatedly and across a program/portfolio?

	these services/reports as an investment to Massive Bio and Sponsor relationship. 1. Number of patients on-board 2. Number of patients consented 3. Number of patients tested 4. Number of patients to be tested 5. Number of patients pre-screened 6. Number of patients eligible (full or partial eligibility) 7. Ineligibility reasons (why patient doesn't fit to the I/E criteria) 8. Number of patient in last mile 9. Number of patients referred 10. Number of patient enrolled <u>Tracking System and Deliverables for Patient Enrollment:</u> The patient is identified, pre-screened, and referred to the Sponsor site by Massive Bio. When the patient signs informed consent of the study and gets the first dose, then Massive Bio bills enrollment fees. For all patients referred to sites by Massive Bio, Massive Bio will provide a tracker including date of referral, site ID, patient ID, etc. The reporting requirements will be finalized based on Sponsor's reporting needs and requirements during due diligence. Key Deliverables: - Detailed pre-screening Collection of medical records and diagnostics labs results Structuring of information and detailed pre-screening with AI Case management support to review results with patients - Enrollment enablement Discussion with treating oncologist Scheduling meetings with treating oncologist and PI Analysis of patient's insurance against patient's referred site Escalation of financial issues to the Sponsor - Customer support Receive incoming patient calls, provide education and engagement.	

	Do the initial pre-screening with digital pre-screener to evaluate which patients need to be escalated to medical records and case management Sponsors leverage MB for several value-ROI reasons, including but not limited to: • Making an analytics-driven and PI-engaged site selection given known and emerging challenges • Leveraging the Hematology and Oncology platform to optimize campaigns and enrollment efforts, while providing Sponsor deeper discounts across trials in similar indication/biomarker/line of therapy • Increase number of patients recruited/screened in each of the Sponsor studies, particularly in the US and high yield countries. Sponsor does not wish to increase site burden by referring ineligible patients to sites. • Be adapted to patient's standard of care, including challenges due to line of treatment status, biomarkers, country requirements, and competing treatment and trial options. • Be cost effective. Each deployed activity should have a clear rationale. • Be measurable and improved based on results, while differentiated from any other vendors. • Take advantage of the unique mechanism of action across the oncology portfolio pipeline and leverage it to engage PIs and referral physicians via direct interactions, and to identify most suitable sites, campaigns, and referral network. • Be analytics and data-driven, with strong patient support and expert oncology research team. • Activate multiple direct-to-patient channels and referral networks, while supporting Sponsor and investigators. • Have been proven successful in the past for a similar indication and line of therapy setting.	

IRB Services	• We provide country-specific materials to IRB regarding Massive Bio services, at no additional cost, and to be submitted by CRO and/or Sponsor (if no CRO involved). We do not prepare other IRB related documents, as they are usually done by CROs. • We have no restrictions in IRB selection or Ethics Committee in any of our 12 countries of operations. • Materials produced within first 4-8 weeks from SOW activation, prioritized based on country.	• Do our services include preparing submission materials to IRB? Is that typically included or an extra fee? • Do we have to use a specific IRB? (local or central considerations?) • Sample timeline for materials.
Company Info	Massive Bio https://massivebio.com/'s mission is to provide access to clinical trials for every cancer patient regardless of his/her location and/or financial stability. Massive Bio is an AI-driven platform connecting cancer patients and their oncologists to bio-pharmaceutical clinical trials, yielding profound improvement in access and match rates, leading to faster drug development timelines, and creating a novel oncology data ecosystem for improved protocol design and real-world insights. Massive Bio controls the patient enrollment value chain starting with patient identification, following with AI-based virtual pre-screening outside the site, and resolving last mile issues for clinical trial enrollment. While improving cancer patients lives, Massive Bio serves close to two dozen pharmaceutical companies, contract research organizations (CROs) and hospital networks. In addition, Massive Bio has been awarded an SBIR contract by the National Cancer Institute (NCI) to develop and characterize its Deep Learning Clinical Trial Matching System (DLCTMS), Contract No. 75N91020C00016. Massive Bio provides oncology dedicated patient recruitment, site selection, real-world data services, and AI-based trial prescreening services to its enterprise customers. Massive Bio was founded in 2015, is headquartered in NYC, and is privately funded by strategic and financial investors. Massive Bio Massive Bio launched industry's First NASA-Style, Oncology clinical trial command center to disrupt and accelerate trial enrollment, featuring 72-hour instant enrollment from time of patient identification in January 2021. Massive Bio has close to 100	Overall company info.

	employees globally (50% US and 50% OUS). Our main office is in New York. We have presence and full operations in US, Brazil, Canada, France, Germany, Greece, Israel, Italy, Poland, Romania, Spain and Turkey. Main Contact is Selin Kurnaz, PhD CEO and Co-Founder Massive Bio, Inc. m: +1 (734) 262-1020 e: skurnaz@massivebio.com 90 West Street, #12M NY, USA, 10006	
Technology advantages?	Clinical Records optimized retrieval, Optical Character Recognition, Natural Language Processing, and Entity Recognition, including through our iOS and Android App, and Customizable Online Reporting Platform. We leverage patients searching and/or participating in clinical trials and real-time patient activation, from existing and non-contracted clinical trials, using Massive Bio's SYNERGY-AI registry (https://clinicaltrials.gov/ct2/show/NCT03452774). Massive Bio is the first organization that has established AI based registry for biomarker-based studies. Criteria as defined in Sponsor already part of existing machine learning matching algorithms in SYNERGY-AI leveraged within Massive Bio's Deep Learning Clinical Trial Matching System (DLCTMS). We are completely site-agnostic, Sponsor tailored, customizable in reports, and fully operational in all countries of coverage. Our approach provides 3-4x fold improvement in recruitment rates, it has been assessed by the NCI, and it requires no expensive implementation or EMR integration. Fully developed oncology and hematology ontology, biomarker and genomic variant repository.	We mention our ever evolving proprietary technology we own and use, and its advantages and effectiveness.
Additional deliverables (beyond patient referrals)	<u>Trial Startup:</u> - Outside in analysis of site patient counts and prioritization of sites - Interview with select sites and understanding of their referral network interaction - Identification, validation, and prioritization of potential referral sites	Here we describe things like identifying sites, patient education, site support, patient support, diversity, DCT, etc.

	- Digital marketing set-up and social media group activation - Identification of patient advocacy groups and start reach-outs - Set-up of patient recruitment workflow and hand-over process - Study support center readiness set-up <u>Monthly Project Management:</u> - Advertisement fees - Digital community formation fees - Management of patient advocates on-boarding patients - Management of provider engagement team to educate referring physicians - Management of case management staff overseeing pre-screening - Management of last mile team members who are providing concierge enrollment (site coordination, logistics and finance) - Management of community engagement team that reaches out to patient advocacy organizations - Management of team that reaches out to payers, specialty pharmacies and data partners - Management of client coordination and reporting <u>Site Selection and Optimization Services:</u> Identification, validation, and prioritization of potential new sites - Estimation of potential enrollment based on site patient volumes - Nationwide hospital rankings based on weighted score of potential to deliver the largest amount of patients - For sites already selected, optimization services include analyzing the patient enrollment potential in the current sites	
Value statement / why work with you?	Massive Bio has a successful track record working with more than two dozen pharma sponsors/CROs, 1,500+ hospitals/research academic centers and on-boarded more than 100,000 patients through its patient contact center to pre-screen for oncology clinical trials globally to-date.	What are key topics as far as the value we can bring? We mention experience and analytics in your closing summary. Case studies also will be shared for completeness.

	• Screening cost reduction
	  ○ Planned screening cost per patient = 33X$750 = $24,750
	  ○ Massive Bio's screening cost per patient = 23X$750 = $17,250
	  ○ Screening cost reduction = $346,500 - $241,500 = $105,000
	• Site cost reduction
	  ○ 4 sites saved.
	  ○ Annual cost per site = Activation ($35k) + Ops (15k) = $50k
	  ○ Site cost reduction = $200k
	• ROI and Total cost reduction = $305k, in addition significant operational simplification (12% site reduction + 140 less screenings) and time gain (3 months earlier than planned enrollment deadline)
	• Deep Expertise in Oncology and Malignant Hematology, including multiple publications showing its value and ROI, across Phase I,II,III and IV studies
	• Unique patient acquisition channels (specialty pharmacy, provider networks, payors, digital health companies, mobile app)
	• End-to-end data-based patient tracking and real-time referral identification, full pre-screening
	• Funnel transparency based on deep analytics and easy to understand project management and reports
	• Biomarker based testing navigation, deep relationships with key NGS vendors and large volume institutional LDTs
	• Integrated diversity and inclusion-oriented patient volumes
	• Only platform contracted by the NCI to integrate with NCTN, NCORP and designated comprehensive cancer centers
	• Only oncology dedicated patient recruitment company in the market with global expertise and fully approved process across US, Canada, Latin America and EU countries
	• MSAs executed with most CROs for fast startup, contract, and procurement process	

	• Dedicated last mile services to guide patient to successful enrollment • Massive Bio's largest impact is made at earliest stages of the clinical trial planning and deployment. • Our services are deployed in a continuum manner throughout the clinical trial timeline, from inception/planning to last patient in. • We became a de facto 'rescue' solution for at risk studies, particularly around competitive landscapes, close timelines and rara biomarkers and/or disease • Over time, our clients realized the advantages of implementing our services at the delivery and planning phases, including site selection and optimization • Comprehensive all-inclusive rates for the duration of MSA/SOW	
Case studies and presentations (put in file names and attach along w this file)	**Will be attached to message.**	
Massive Bio Innovative Proposal and Capabilities Overview Summary 1.2023.pptx		
Massive Bio Case Studies 1.2023		
Card Rate		
Case Studies		
Links to videos or web sites, etc.	**Link description**	
https://massivebio.com/	Main Website	
https://themedicinemaker.com/discovery-development/cancer-clinical-trials-the-wheres-waldo-puzzle-no-one-wants	Cancer Clinical Trials: The Where's Waldo? Puzzle No One Wants | Massive Bio co-founders Selin Kurnaz and Arturo Loaiza-Bonilla discuss the difficulty in finding candidates for oncology clinical trials	
https://www.businesswire.com/news/home/20221007005068/en/Massive-Bio-Nominated-for-Prestigious-Digital-Health-Award	Massive Bio named a quarterfinalist in the annual UCSF | Health Hub: Digital Health Awards, which recognize health tech companies that are driving innovation and improving delivery of healthcare	
https://www.outsourcing-pharma.com/Article/2022/10/17/massive-bio-partners-to-use-ai-for-oncology-clinical-trials	News about use of AI for clinical trial enrollment	

https://www.marktechpost.com/2022/06/25/meet-massive-bio-an-ai-powered-oncology-platform-that-connects-patients-to-clinical-trials-while-enabling-pharma-to-get-access-to-patients/	Meet 'Massive Bio', An AI-Powered Oncology Platform That Connects Patients To Clinical Trials While Enabling Pharma To Get Access To Patients	
https://www.businesswire.com/news/home/20221026005381/en/Massive-Bio-Onboards-Over-100000-Cancer-Patients-to-Find-Their-Clinical-Trial-Powered-by-Artificial-Intelligence	Massive Bio onboards over 100,000 cancer patients using artificial intelligence, empowering patients to find treatment options faster	
https://www.businesswire.com/news/home/20221110005477/en/Massive-Bio-and-Azra-AI-to-Expand-AI%E2%80%99s-Potentially-Lifesaving-Impact-on-Cancer-Patients	Massive Bio and Azra AI to Expand AI's Potentially Lifesaving Impact on Cancer Patients |New partnership brings accurate trial recommendations to Azra AI's national client base of medical systems and hospitals, including leading healthcare providers	
https://www.youtube.com/@MassiveBio	Massive Bio YouTube Channel	