Is your organization "precision-medicine workforce ready"?

THE CHIEF CAT HERDER OF PRECISION MEDICINE

by Franziska Moeckel

Most people know that finding the right talent is never easy; however, finding the right, specialized talent is even more challenging. Although much clarity and publicity has been brought to what is now widely called *Precision Medicine*, we are continuing to define and develop the promise of Precision Medicine becoming part of mainstream medicine.

Global investments in sequencing the human genome have led to many technological advancements and scientific breakthroughs. These applied science developments have led to implementation and application of novel technologies and medicines in clinical care within healthcare institutions. However, no one has yet found the textbook format for a sustainable, economically viable, and reproducible precision medicine program or the blueprint for precision medicine integration. Variances in critical areas such as reimbursement, physician acceptance and adoption, testing technologies, consumer (market) demand and understanding, and standards of practice (based, in part, on the federal, national, regional, and local regulatory landscape) make the formation of a uniform adoption model challenging.

Fortunately, the quest continues and is not slowing down. However, to fuel progress sufficiently, institutions must invest in an important but too often overlooked aspect of building successful programs – the selection and grooming of the right talent.

The Paradigm Shift: Precision Medicine is no longer just for researchers and clinicians

Human capital is at the foundation of every successful organization and often is simply an assumed part of an established industry. Yet the search for the right talent can be hard, time-consuming, and costly – especially when it comes to setting up or expanding specialized programs like precision medicine. It is no secret that in order to recruit intentionally and selectively, it is important to understand the requirements for being successful in creating a precision medicine workforce. To understand the requirements, one must understand the industry and market forces. In precision medicine, a lot of this is continuously evolving.

Leading healthcare organizations – academic medical centers, integrated health systems, and community-based hospitals alike – have made major investments in the field of precision medicine. Workforce investments have primarily been made in hiring lab staff to build up in-house molecular testing capabilities; MD PhDs to set up genomic research programs and clinical trials; expert clinicians to establish specialized precision medicine programs and clinics (such as in oncology and pharmacogenomics); and genetic counselors to support and guide the clinical decision-making process. Yet, the difference between being a first mover and fast follower in the field tends to be the ability to tie it all together, namely, finding clinically meaningful and economically

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Having this capability within a healthcare system contributes to the success of the entire precision medicine ecosystem –including diagnostic companies, biotech and pharmaceutical companies, clinical laboratories, and other life sciences firms. Arguably, healthcare systems can become the epicenters where most, if not all, precision medicine capabilities meet and find application, but perhaps more importantly, where outcomes can be measured.

Operationalizing a precision medicine program entails, amongst other things: selecting precision medicine features for your patient

Table 1: Precision Medicine Program Categories & Components

Category	Objective	Components
Legal, Compliance, and Risk Management	Understand the legal forces at play – including GINA, as well as managed care coverage determinations including but not limited to ICD-10 and CPT codes. Familiarity with evolving regulatory issues around data storage and sharing, incl. the use of data for research.	• Federal & State Laboratory Regulations
		• Reimbursement
		• Genetic Information Nondiscrimination Act of 2008 (GINA)
		• Data Sharing and Protection
		• Data storage, retention and maintenance
		• Informed Consent & Research
Information Systems & Technology	Possess ability to assess, compare, select, and negotiate the right IT solutions for your institution and understand organizational requirements – including the ordering and resulting of tests, lab requirements, and EHR system integrations.	• Lab / EHR systems integrations
		• Physician / Patient Portals
		• Report view & Result returns
		• Housing of genomic data
Reimbursement / Payment	Have an understanding of essential reimbursement and payment structures. These may include Centers for Medicare and Medicaid Services (CMS) local coverage determinations, managed care contracting, as well as cost, pricing and claims processing strategies.	• Managed Care Contracting; Coverage Determinations; payer negotiations
		• CMS; Lab fee schedules
		• Cost / Pricing
		• Claims processing
		• Payment collection systems
Education / Outreach / Marketing & Communications	Develop provider education – including physicians, pharmacists, nurses, lab techs, and the entire clinical support team, as well as genetic counselors. Obtain continuing medical education credits. Build a strong communication and marketing plan for clinicians, patients, and employees. Enhance patient care and brand.	• Physician / Pharmacist / Clinical support team / genetic counselors
		• CMEs
		• Branding
		• Trademarks
		• Community
		• Employees
Operations (Laboratory & Hospital)	Set up underlying functions and systems that dictate laboratory and hospital workflows for precision medicine tools. No interruption to existing workflows. Orchestrate and connect work of many teams. Consider various standard operating procedures.	• Laboratory: Buy vs. make decisions
		• Hospital: Workflow integration
		• Project management
Strategic Planning	Complete thorough market assessment and researching local, regional, and national market forces that may drive implementation decisions. Investigate payer mix, patient volumes per service line, ROI calculations, etc. Collect, vet, analyze, and validate data through pilots and case studies. Manage and select vendors based on needs assessment. Make test buy versus make decision. Vet external partnerships.	• Market assessment
		• Data analytics
		• Vendor Management
		• Partnerships
		• Market assessment / competitive analysis
Research & Provider Integration	Facilitate beneficial research partnerships and provider integration. Have strong organizational connections. Select physician champions for integration of specific precision medicine solutions. Set up advisory boards comprised of clinicians and non-clinicians.	• Integration network & Advisory Boards
		• Physician champion selection
		• Pharmacy

population; conducting economic feasibility studies (including *buy* versus *make* decisions for in-house laboratories); creating physician and patient education modules; calculating and setting product/service costs, rates and prices; understanding and negotiating managed care contracts; designing marketing and communications plans; assessing ethical, legal and risk management, as well as compliance implications of genomic testing (see **Figure 1**).

The introduction of a new precision medicine feature in a healthcare system is comparable to a product launch. For the time being, the clinician and scientist will remain the experts of genomics and its application to patient care. The role of bringing precision medicine tools and knowledge to the bedside will transition to a subset of professionals (clinical and non-clinical) who currently understand the complexities and intricacies of making a clinical precision medicine program operational. In particular, the next generation of healthcare administrators will have an integral role in impacting success from behind the scenes and will be at the cusp of precision medicine integration.

Until we have established a scalable blueprint for precision medicine integration and validated the first operations-driven precision medicine system, we must work diligently to develop and evaluate precision medicine curricula at universities, business schools, and medical schools. Furthermore, we should look for entrepreneurs with a start-up mentality, institutional savviness, an ability to assess innovations such as new devices or solutions, and passion for the science of genomics. In this article, these entrepreneurs are referred to as the "Chief Cat Herders" of precision medicine.

The Chief Cat Herder of Precision Medicine: Finding the jack of all trades

Next to clinicians and researchers, business operations leaders are one of the key implementers of next-generation technologies, therapies, and testing. But why are business operations leaders such an important part of the equation? And how will you write the right position description and find qualified talent for your precision medicine team? Of note is that physicians often serve in a dual role – that of a clinical and business leader. If no such role for a precision medicine department exists in your organization or if you have been recently selected to co-chair a precision medicine program with a business and clinical lead, the following recommendations might be of help to you.

First, recognize that the role of Chief Cat Herder is to enhance the capabilities of your clinical team by focusing on administrative and business operations responsibilities. He/she should know or be familiar with the intricacies that make or break a successful product or service implementation at the organizational-level. He/she should not only manage different personalities (and competing priorities and demands) but also set realistic expectations and goals, manage risk, be creative and resourceful, educate on-the-go, facilitate inter-disciplinary working groups, and be able to speak about genomics in an informed manner (and know when to defer to scientific and clinical experts.)

The Position: Other duties as assigned

The key to hiring a precision medicine "A-Team" is to understand the position requirements and constraints. Although much of the tasks can be specific to your organization (when you have seen one precision medicine program you have seen one precision medicine program) and can often be ambiguous, there are common themes that apply to most if not all programs (see **Table 1**).

Based on these themes, we recommend the following considerations when recruiting candidates to introduce a centralized precision medicine program and establish administrator-type roles to support the clinical-physician teams and drive the operational aspects of care integration. While candidates may not be an expert in all of these areas, it is essential that they understand the breadth and complexities of the position duties:

- **Legal, Compliance, and RiskManagement**

It will be beneficial to have a foundational understanding of the legal forces at play – including federal and state regulations, as well as of the Genetic Information Nondiscrimination Act of 2008 (GINA.) Managed care coverage determinations, including but not limited to ICD-10 and CPT codes, must also fit in the repertoire of a business leader's knowledge. Evolving regulatory matters around data storage and sharing of information (including the use of data for research) are other issues that will be of importance for the business leader to understand.

- **Information Technology**

In order to assess, compare, select, and negotiate the right IT solutions for your institutions, it is of tremendous importance to understand the requirements your organizations has – including the ordering and resulting of tests, lab requirements, and EHR system integrations.

- **Reimbursement / Payment**

As part of building a sustainable program, having an understanding of essential reimbursement and payment structures, including Centers for Medicare and Medicaid Services (CMS) local coverage determinations; national coverage determinations followed in managed care contracting; and cost, pricing and claims processing strategies.

- **Outreach & Education, Marketing & Communications**

A strong outreach and education program is just as important as creating a comprehensive communications and marketing plan. This may include but not limited to, providing ›

Figure 1: Precision Medicine Program Categoreies

education for physicians, pharmacists, nurses, lab techs, and the entire clinical support team, as well as genetic counselors. Continuing medical education credits are an effective tool in obtaining interest and response.

A strong communications and marketing plan must be built out in order to communicate effectively not only with clinicians but also, and perhaps most importantly, with patients. If done well and communicated appropriately, your services will not only advance and improve patient care but can also enhance your brand.

Operations (Laboratory and Hospital)

Perhaps one of the most critical aspects of managing and setting up a working precision medicine program is operations. The underlying functions and systems that dictate laboratory and hospital workflows must be studied thoroughly before making any implementation decisions. It is essential that existing workflows not be interrupted by bringing new, innovative solutions to patient care. A seamless workflow requires the orchestration and connection of multiple work-streams of many teams as well as the consideration of various standard operating procedures. Consultation with staff leaders and staff members must be included throughout the process to solicit ideas, review changes, communicate changes, and train accordingly.

Strategic Planning

Part of developing a strategic plan for precision medicine integration is based on a thorough market assessment and researching local, regional, and national market forces that may drive implementation decisions. Payer mix, patient volumes per service line, ROI calculations, etc. will drive the value equation of precision medicine. Data should be collected, vetted, analyzed, and validated through pilots and case studies.

Based on the analysis, vendors should be selected and managed accordingly. If your organization has an in-house genomics laboratory, buy-versus-make decision will be the responsibility of the business lead. Developing external partnerships must be vetted thoroughly; for instance, one must conduct a focused due diligence analysis before committing your organization to another pharmaceutical company that will have sole access to your data.

Research and Provider Integration

In order to facilitate beneficial research partnerships and provider integration, a strong organizational network can help make connections. Physician champions are essential for the integration of any precision medicine solution. An advisory committee comprised of clinicians and non-clinicians can serve as a sounding board for new efforts.

The Position Description: A template

While the themes cited provide a guide to position requirements, it is the unknown, the implicit opportunity of a blank slate that often draws talent trained in business applications to new opportunities, such as offered by precision medicine. One should not shy away from leaving "other duties as assigned" as an ambiguous section on a position description and potential outlet to unleash creativeness while seeking hard business skills. When thinking about drafting a position description, the following may serve as a potential summary:

Position Description for [Chief Cat Herder]

Responsible for all operational and business aspects for the clinical integration of the

research achievements and discoveries within the organization, this role will lead the commercialization and operations of new precision medicine services in all clinical care settings. This includes the marketing, branding, and promotion of all precision medicine initiatives.

In this role, the [Chief Cat Herder] evaluates and manages new strategic business opportunities, initiatives, mergers, acquisitions, partnerships, alliances and/or joint ventures for the organization as it pertains to precision medicine. The [Chief Cat Herder] oversees market analysis, monitors competitive activity, and identifies customer needs while providing leadership in the planning, designing, due diligence, and implementation of strategic business objectives. This role is integral in defining a precision medicine vision, strategy, and related tactics and manages a team to reach these objectives.

Key Responsibilities may include:

1. Co-developing the strategy for precision medicine in partnership with the clinical leadership team at an organizational level.
2. Establishing precision medicine committees to create clinical and business review bodies.
3. Chair the precision medicine business committee and establish business justifications, business plans, and go-to-market strategies for all new precision medicine initiatives.
4. Leading the incorporation and application of the precision medicine strategy on a company-wide basis.
5. Aligning precision medicine strategies with those of the clinical service line leadership team(s) and serve as a liaison to ensure accountability for strategy execution.
6. Promoting the visibility of a Precision Medicine program and related activities.
7. Developing distinctive precision medicine offerings to differentiate and drive business to destination services.
8. Working with the senior leadership team to develop precision medicine services aligned with the organization's vision and mission, including the delivery of precision medicine services at a system-wide level.
9. Overseeing integration of precision medicine, operationalizing services in care practices.
10. Setting up and facilitating an interface with the organization's business, legal, finance, operations, information systems, and marketing / communication teams to drive discussions with both internal and external audiences to ensure alignment, adoption, and messaging of precision medicineinitiatives.
11. Leading or supporting creation of new genetic/genomic test offerings, including but not limited to designing a product roadmap, pricing strategy, and clinical program integration masterplan.
12. Assisting with the assessment of all business contracts including the identification, evaluation and, if applicable, the acquisition of potential partners/vendors related to precision medicine.
13. Oversee the precision medicine business team.

What's next: Finding your Chief Cat Herder

These and other characteristics can be helpful when thinking through the components of precision medicine integration and structuring a search for the right talent. Understanding the industry, market forces, and position requirements needed to set up a strong team is the foundation to any successful program. It will be hard to find an individual who, at the onset, will know about all of these capabilities, especially since there are vast differences between organizations, states, and patient groups. Many talented individuals are ready to take the next career step to make a meaningful impact in the lives of others and are not afraid to try new things knowing that the majority of innovations fail. Fortunately, the precision medicine community is a close-knit group and is ready to share experiences, best practices, and lessons learned widely for the benefit of furthering the progress of personalized patient care. ■

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Ms. Moeckel has successfully operationalized precision medicine programs, including legal and risk assessments, IT systems integration, managed care payer reimbursement, marketing & communications plan, as well as operations & workflow development.

She is the recipient of the 2018 Greater Washington Health & Life Sciences Innovator of the Year award, the George Mason University School of Business Distinguished Alumnus of the Year and Alumni Exemplar award. With over a decade of healthcare experience and a deep understanding of precision medicine integration, Franziska is a respected thought leader in the field and consults on best practices for many national organizations.

Franziska earned her Bachelor of Science degree from George Mason University's School of Business. She earned her Master's degree in Business Administration from the University of Maryland, as well as a Certificate in Genomic Medicine and Bioeconomy from the Harvard School of Public Health. She has been published in peer-reviewed journals and trade magazines, quoted in industry-related books, and serves on multiple national panels and boards.

In her free time, Franziska enjoys traveling to exotic destinations, including dancing with the Masai in Tanzania and Kenya, and spending time with her family in Germany.