PRA Health Sciences

WHITE PAPER

A Shift in Thinking: How Investments in Supply of CRAs is Better than Competing with Demand for CRAs

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Executive Summary

The demand for experienced CRAs has been a challenging problem for the industry for at least the past two decades. It has been precipitated by the rising scale and complexities of clinical trials, heightened regulatory scrutiny and the significant increase in competition for trial patients in certain geographies. The number of sites, patients and data points collected has risen significantly all of which serve to increase CRA demand. This problem is exacerbated by the substitution of experience as a surrogate for CRA competence; a substitution that only amplifies the demand pressure the industry is experiencing. With regard to supply, there is a lack of talent available to fill these roles and meet the growing demand. This "talent drought" is the result of several factors: 1) increasing demand; 2) slow adoption of technologies and processes that will drive efficiency in the monitoring process; 3) a focus on experience over competence; and 4) the inability of the industry to effectively grow talent to meet current and future trial demands. This paper seeks to address the CRA supply side of the equation. We will review a number of programs available that serve to enhance CRA competence and, importantly, access latent talent pools which can increase the supply of qualified CRAs. We will show that these CRAs generally have greater retention rates and have as good if not better performance ratings across a variety of measured CRA skill sets. Finally, we will review a model where these CRAs can be introduced into sponsor projects with a planned and thoughtful discipline ensuring that project and functional delivery remains at or above the quality and process standards required for a successful regulatory review.

Introduction

One of the first concepts reviewed in any introductory macroeconomics course is Adam Smith's theory of the Law of Supply and Demand[1]. With this law, Smith was able to simplify often complicated economic concepts and, in the case of supply and demand, his fundamental points were simply:

- As demand for a scarce resource *increases*, price for this resource will *increase*
- As supply for a scarce resource *increases*, price for this resource will *decrease*

In short, supply and demand are inversely related to each other. While perhaps an obvious statement at first, this point become more interesting when we consider that supply and demand are not fixed and are further complicated when we factor in the value the consumer ascribes to the resource itself. This value is the market price and reflects the equilibrium between the supply and demand (Figure 1).

The Clinical Research industry is not immune to these forces and this is perhaps no more evident than in the seemingly constant shortage the industry has for experienced Clinical Research Associates (CRAs). It is common knowledge that the demand for CRAs has significantly outpaced supply over the past two decades and we have seen the corresponding price increases that Smith would predict. The average starting salary for a CRA, with no experience, in 1992, was around $27,000 a year. Today, that average starting salary is around $80,000 a year or nearly $30,000 higher than 1992's salary when adjusted for inflation.[2] We believe this confirms that demand for CRAs has outpaced its supply.

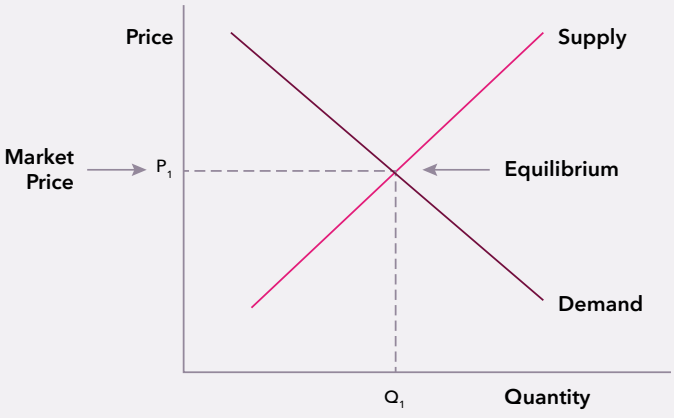


Figure 1

CRA Demand Pressures

The demand for CRAs has increased for a variety of reasons. Clinical trial data volume has risen in both scale and complexity as new and more complicated scientific assets are advanced in our customer portfolios. Site and patient numbers have been increasing steadily since the early 1990s as sample sizes rose to reveal more subtle treatment effect differences from more active controlled trials. With the more recent introduction of biomarkers as inclusion criteria and endpoints, we are now beginning to see a reduction in the number of patients required per clinical trial (and far fewer large, outcomes trials being conducted) though the number of sites per trial remains relatively unchanged. In addition Covid-19 has demonstrated that the adoption of available technologies can make clinical monitoring more efficient and it will be interesting to see how the Regulators operate as we exit the pandemic.

These factors have increased the net demand for CRAs with the preference for experienced CRAs rising even faster. This serves to increase the demand pressure and, if we consider supply as fixed, this will increase the price to the customer as shown in Figure 2.

While many of these demand pressures are real and a consequence of the increasing complexities of clinical trials, there are a number of additional factors to consider that may inadvertently increase demand pressure for CRAs. For example, many of our large pharma partners use large, embedded (FSP) sourcing models to enable a variable workforce. Many of these models are multiple supplier models and, in the interest of ensuring "healthy competition" between suppliers for speed and pricing, a request for a CRA will often be made to all suppliers simultaneously. This can amplify the demand significantly as, in a 3 or 4 supplier model in the same market, the market itself will reflect a demand for 3 or 4 CRAs even though that demand traces itself back to the single request by the customer. A result which would increase CRA demand by a factor of 3 or 4 fold. It was estimated in 2018 that the industry had a shortage of over 17,000 CRAs globally[3]. What is unclear is how many of these demanded CRAs are a consequence of this type of amplification.

We believe that another source of demand pressure may be the requirement to use experience as a surrogate for competence when requesting CRAs. In our experience, while we understand how experience may be indicative of a CRA's competence, it does not guarantee a competent CRA; particularly as new technologies and processes like Risk Based Monitoring gain adoption in clinical research. CRA competency assessments exist that allow a direct measure of a competence, regardless of experience though these are infrequently used during the CRA recruiting and hiring process. Finally, as CRA turnover is one source of CRA demand, mandating a level of experience can serve to increase turnover risk as, by design, these experienced CRAs will have shorter time in role before wanting to move on to the next role in their career. This compounds the challenge as supply decreases while demand increases and is often reflected in the large salary differences between a CRA with 1 or 2 years of experience and one with more than 5.

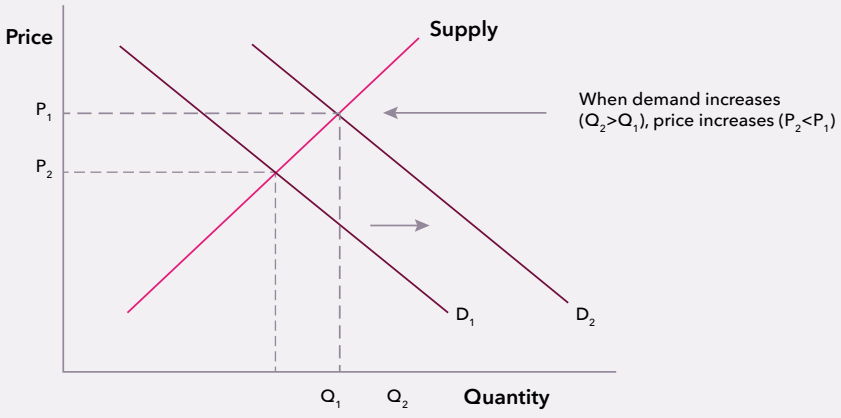


Figure 2

A Focus On CRA Supply

As we turn our focus to supply, we believe success will be driven by 4 main objectives. These include:

1. Accessing latent talent pools of experienced clinical professionals ready to transition into the CRA role
2. Accessing pool of recent college graduates, especially those with life sciences degrees
3. Replacing CRA experience as a surrogate for CRA competence with competency-based assessments to ensure role proficiency
4. Developing a transparent model to introduce these new CRAs into the industry without increasing delivery risk of the customer project or portfolio

A summary of how we have addressed each of these follows below.

The CRA Bridge Program

PRA Health Sciences (PRA) has been delivering basic foundation training for new, inexperienced CRAs for the better part of a decade. In the early days, the volume of participants working their way through this training program was modest and resulted in just enough new CRAs to meet our own demand. However, by 2015, as demand skyrocketed across the industry, we began significantly investing into this program with the understanding that the supply we were creating would be beneficial to the industry as a whole. Today, this program, known as our CRA Bridge Program, is an industry-leading, comprehensive training program that provides core CRA foundation training, practical application, comprehensive mentoring and coaching, and introduces competency assessments to ensure these new CRAs are equipped to excel as CRAs. Since 2015, this program has introduced almost 2,000 CRAs globally into the clinical research industry.

Our CRA Bridge Program has been designed to ensure maximum retention of training material coupled with comprehension checks to ensure knowledge transfers into performance. Through robust and consistent mentorship, structured manager coaching, soft skills development and comprehensive, practical knowledge assessments, we are setting our Bridge CRAs up for years of success.

The CRA Bridge program is highly effective at creating a team of high "IQ" CRAs (as measured by competence) from a pool of high "EQ" individuals. Our talent pool of resources selected for the CRA Bridge Program most typically include study coordinators, research nurses, pharmacists, nurse practitioners, etc. These individuals join PRA with a wealth of experience and ability to develop strong, interpersonal and credible relationships with site staff, i.e. they have a high "EQ". Another valuable resource pool for our CRA Bridge Program is our In-House CRA resources, those with experience on the CRO side of research albeit from the perspective of the study management side. These resources develop into strong "IQ" CRAs and through additional soft skills development and structured mentoring, quickly learn the equally valuable "EQ" needed for success.

As PRA drives toward solving the supply issue with the CRA Bridge Program, we are taking advantage of the opportunity to introduce the next generation of CRAs, those coming from the Millennial and Generation Z communities; a workforce already quite advanced in the adoption of new technologies, applications and digital health. 2020 saw the launch of the first fully decentralized clinical trial; a trial enabled by telehealth visit checks, wearable technology for the study patients, and new ways of monitoring data and patient safety.[4] It changes the communication pathways to manage site requests, queries, enrollment, and study team information. It requires new technology skillsets that even experienced CRAs need to learn; while simultaneously *un*learning the "old way". Our Bridge CRAs are leaping to the front of this new paradigm as they join without any other frame of reference. They are ready to learn without having to first *un*learn.

The next generation of CRAs will need to be fully tech-fluent, comfortable working in remote environments and become stewards of the data as the lines between Clinical Research Associate and Data Manager start to blur. It will also be interesting how the role of the Medical Science Liaison evolves

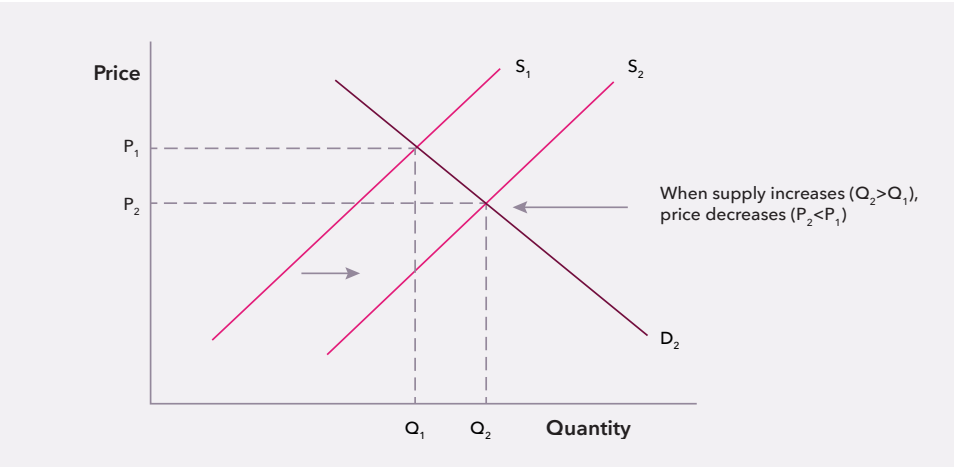


Figure 3

in relation to the work that is performed at site, which could be at an increased academic level. We cannot and should not wait to bring these generations into the industry.

While the CRA Bridge Program has helped increase the industry's supply of CRAs, more needs to be done in this space by all those impacted by these supply and demand pressures. If the industry can work collectively to solve the supply strain and shift from an experience-driven demand to a competence-driven demand, we have confidence that this will ultimately result in a reduction in price for our customers as reflected in figure 3.

Experience versus Competence

In our experience, we have found that customers who prescribed a minimum level of experience for an assigned CRA were actually more interested in the competence of that CRA. There is an implied assumption that CRA experience is a strong surrogate for CRA competence or, put another way, if experience equals competence, then low experience must mean low competence. **We have not found this to be the case.** To be clear, while we believe experience is important and a majority of experienced CRAs in the industry today are highly competent, we also see that through effective training, mentoring, performance and metrics management, our Bridge CRAs with < 2 years of experience can often perform at that same level or higher than CRAs with many more years of experience across the same key performance indicators – thereby demonstrating that they both are objectively, equally competent to do the job.

For 3 years following their CRA Bridge training, we isolate the performance and quality metrics of the Bridge CRAs and compare them to their more experienced peers, looking for any indicators that additional support might be needed. Instead of discovering gaps, however, the Bridge CRAs have consistently shown that their performance matches, and sometimes exceeds, the more tenured CRA; proving again that experience does not always determine competence. This is shown in the figures 4, 5 and 6 which provide the compliance rate comparisons for two important CRA deliverables, the Monitoring Visit Report (MVR) and Follow-up Letters (FUL). Note that compliance in this case means a fully approved MVR and FUL.

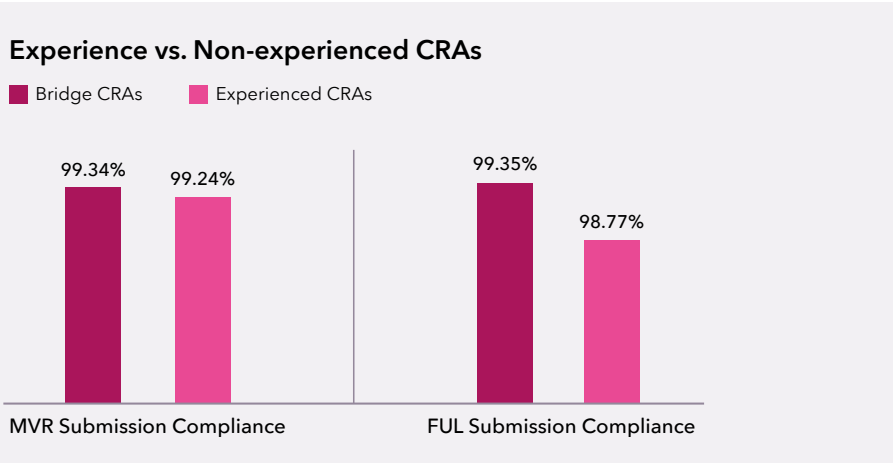


Figure 4

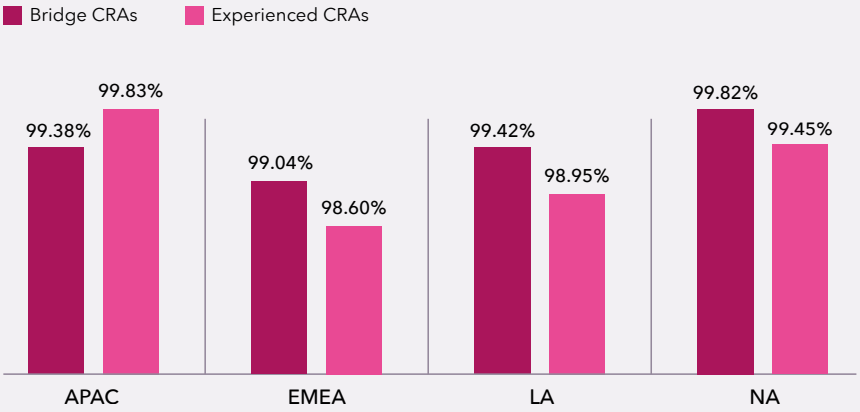


Figure 5

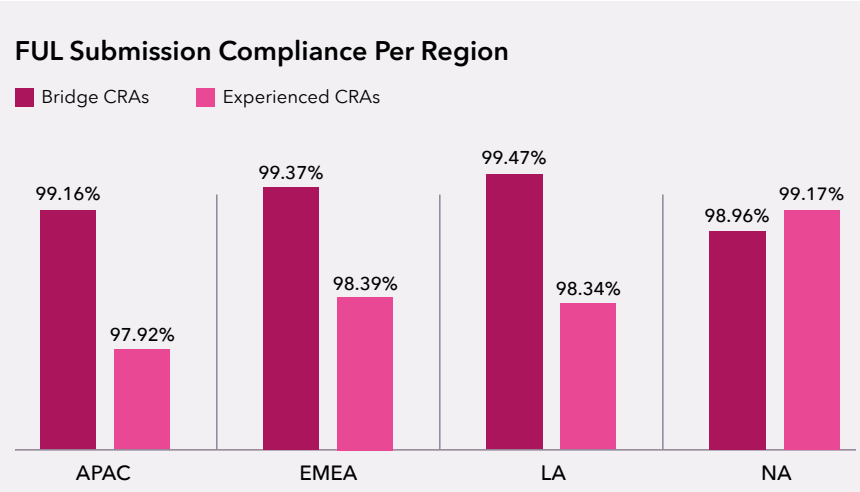


Figure 6

Introducing New CRAs into the Functional Portfolio – The Case for Blended Teams

Perhaps the largest challenge we have found limiting the success of these programs is the reluctance of our customers to accept these "inexperienced" CRAs. It's a Catch-22 as, while we all know that a focus on supply would benefit the industry, many customers specifically request a team of experienced CRAs and, without objective evidence of the CRAs' competence, who can blame them?

At PRA, we look to address this problem within our embedded solutions transparently with our customer partners. These relationships often contain hundreds of PRA CRAs within the functional portfolio and this scale allows us to introduce our Bridge CRAs in a thoughtful and planned basis. For example, we often:

- Maintain a Bridge CRA to total CRA ratio of 15% or less across all CRAs (A Bridge CRA defined as having less than 1 year active monitoring experience. This ensures that we can introduce these new CRAs without compromising portfolio delivery.)
- Commit to performance based KPIs and service level agreements (SLAs) to ensure consistent and acceptable delivery across all CRAs, regardless of type.

The strategies have been used successfully across a number of our embedded customer partners. We have also found that our experienced CRAs are critical to the overall success of our Bridge CRAs. They are these CRAs' mentor, their 'study buddy' and are often asked to support process improvement initiatives. In their role as subject matter experts, they become important contributors to the continued development of our Bridge CRAs. This can have a positive effect on the experienced CRAs as they enjoy this supporting role.

We have been able to rebalance our CRA work force experience without compromising quality on several of our embedded programs. While this has helped PRA satisfy the demand of these customer portfolios, perhaps an even better benefit is the lowering of total CRA spend of 5-10% as this rebalance occurs. As an example, Figure 7 shows the effectiveness of rebalancing the US based portfolio of CRAs over a 3 year period as we moved from a distribution of >84% CRA level 3 (high experience) and <2% of level 1 CRAs (Bridge

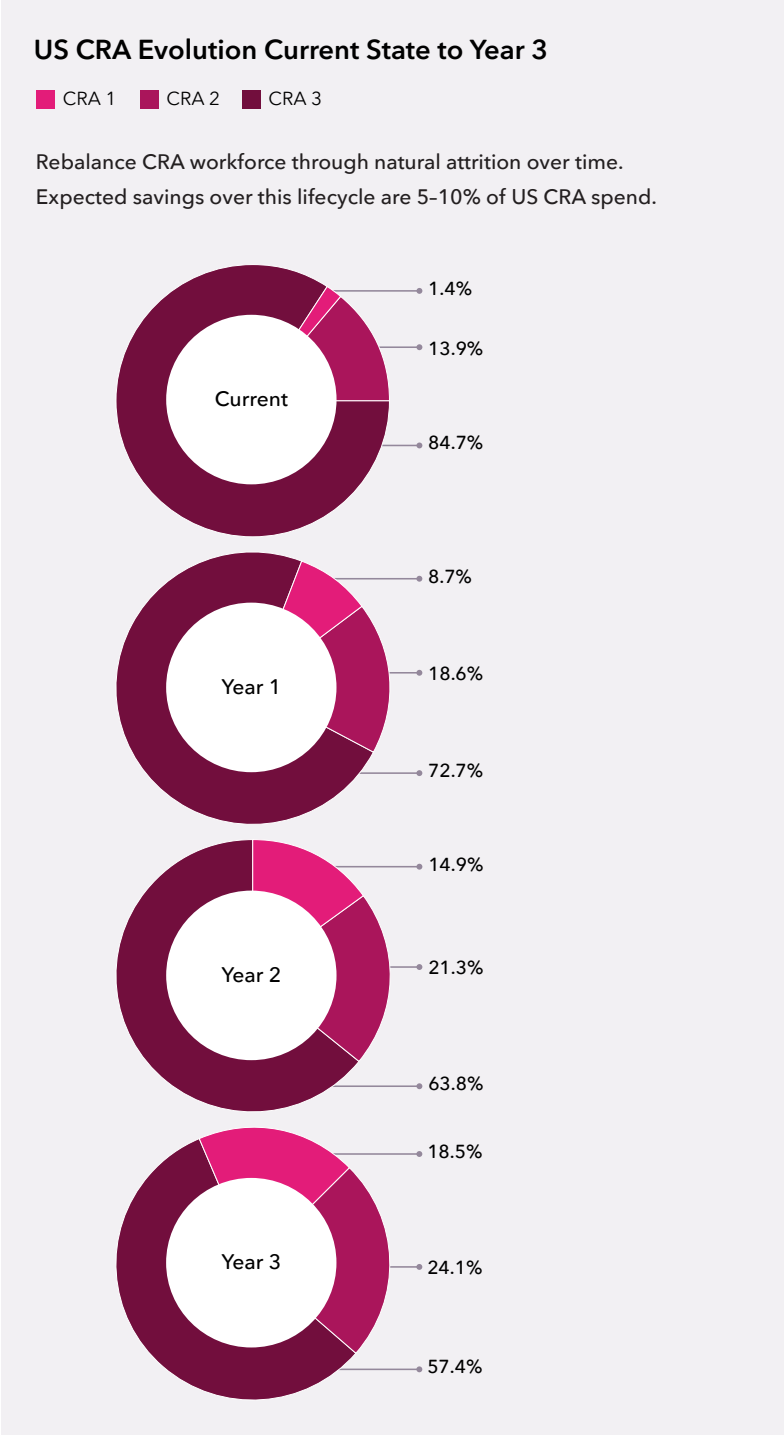


Figure 7

equivalent) to a more balanced model with 57.4% level 3 and 18.5% level 1 CRAs; a rebalancing that occurred without compromising quality or portfolio delivery.

In this example, were able to introduce 97 of our CRA Bridge program graduates into the embedded portfolio. In addition, during this period we also introduced 174 of our Oncology University[a] graduates into the model; a program also attended by 30 of our customer employees. Finally, the Bridge program has been so successful that 30 of the 97 graduates assigned have subsequently transitioned to the customer as full time employees.

Retention and Performance

Perhaps the most critical measures of success with the CRA Bridge program are the usual measures of retention and performance. As we developed the program, our hypothesis was that retention of these staff would be higher, largely due to the fact that experienced CRA staff would have less professional time remaining in the role before wanting to move on to the next phase of their career. We also expected to show that the performance of these staff would be similar to the performance of our experienced CRA team members. As shown in figure 8, CRA retention in the program referenced above has been nearly 95% and compares favorably with the retention rate of 89% for experienced CRAs within the same program.

As important, figure 9 shows the performance distribution of our CRAs across our corporate performance categories of Low (1.0), Full (2.0) or High (3.0) performance As this figure shows, we have found no differences in the performance between the 2 CRA groups and in fact see that the Bridge CRAs tend to perform slightly higher than those with more experience.

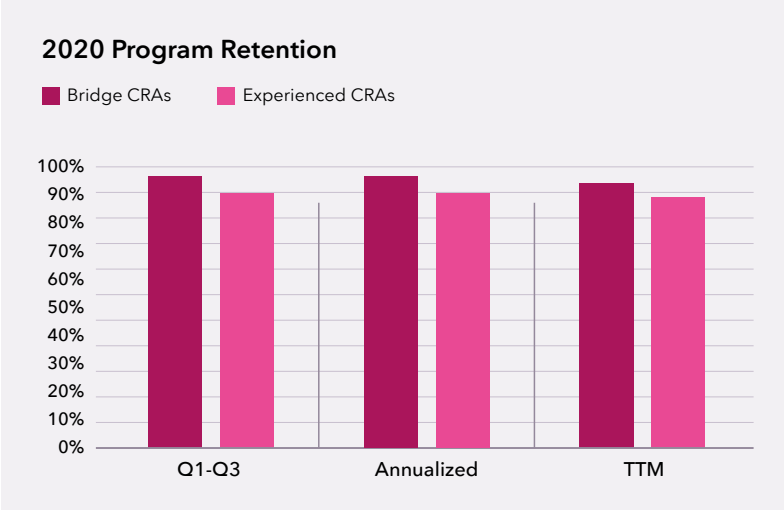
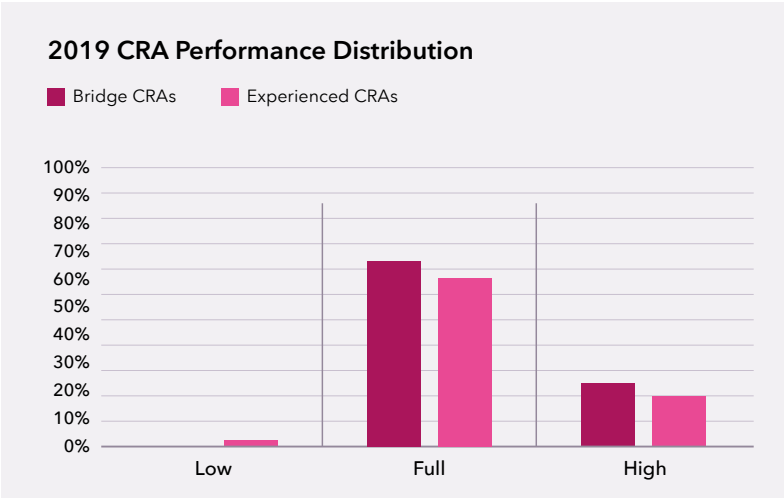


Figure 8



Rating	Bridge CRA	Experienced CRA
Low	0.58%	0.90%
Full	71.30%	65.40%
High	25.70%	19.50%
Average	2.257	2.216

Figure 9

[a] The Oncology University is a training program designed to prepare CRAs for the additional requirements of working on oncology trials.

Summary and Conclusion

PRA's CRA Bridge program has introduced over 2,000 CRAs into the clinical trial ecosystem over the past 5 years. Many of these CRAs remain with PRA, deployed as CRAs across several of our customer embedded models. These models have seen not only the economic benefits of these less tenured CRAs but also the benefits of lower turnover and demand pressure for this typically scarce resource. The benefits have not been accompanied by the increase risk often associated with the use of less experienced CRAs, particularly as we replace experience with competence as an entry qualification. PRA's shift in investment focus from competing with the demand for CRAs to investments in the supply of CRAs has generated material benefits for both our customers and PRA.

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