

Background

Scoring guide development:
A tiger team was created to develop a weighted scoring system to score protocols during PRMS review in alignment with the UCDCCC strategic plan. The team developed five unique categories to rank protocols between 1 and 5. Each of these categories is then multiplied by a weighted factor depending on the category's placement of importance within the strategic plan. The total score for each category (ranking multiplied by weighted factor) is added together for a cumulative protocol score that is translated to be either a low, medium, or high score. Disease Teams can endorse any protocol, with low scoring protocols needing further justification provided to SRC.

Category	Low (1)	Med-Low (2)	Medium (3)	Med-High (4)	High (5)	Raw Score	Weight	Total Score
Scientific Interest*	Modification from standard therapy (e.g., dose, route or frequency)	FDA-approved agent in another indication or PI; exempt	Conducted under an IND/IDE	Early phase (I or II) trial and/or includes research programmatic collaboration	Personalized medicine strategy, or any high impact potentially practice changing trial	5	3	15
UCDCCC Annual Accrual Potential	< 3 patients	3-9 patients	10-19 patients	20-29 patients	≥ 30 patients	5	3	15
Investigator Input/Academic Credit	Industry authorized with no investigator input or authorship potential (site PI)	National when investigator input, including participation working group (site PI)	Industry with investigator input (e.g., steering committees, etc.)	UCD investigator authored institutional (multi-site PI) and/or UCD holds the IND or	UCD investigator authored and originating from UCD basic science or	5	2	10
Potential for accrual of minority and underrepresented (e.g., rural, ethnic, low socioeconomic status, etc.) patients*	Excludes non-English speaking patients		Protocol is neutral, does not meet the low or high criteria	UCD investigator authored and originating from UCD basic science or	UCD investigator authored and originating from UCD basic science or	5	2	10
Competing Studies/Operational in Development	One or more		Some overlap with current algorithm or planned course that will eliminate conflict	UCD investigator authored and originating from UCD basic science or	UCD investigator authored and originating from UCD basic science or	5	1	5

Sum of Total Score: 55
Weighted Score: 100%
Protocol Priority Score: **High**

Method

Retrospective Analysis:
A retrospective analysis was done scoring the currently active to accrual protocols in May of 2023 with the newly developed scoring system. Protocols were ranked and grouped as high, medium, or low scoring to show a distribution of endorsed protocols.
A prospective analysis of all protocols currently active that were proactively scored by PRMS after July of 2023 was done by pulling data reports from OnCore. Metrics of how many protocols in each scoring level were activated, as well as scoring compared to current total and promised accrual were analyzed. These results were compared to the retrospective analysis for interpretation of scoring guide effectiveness.

Results

The retrospective analysis (Figure 1) shows that a bell curve of protocols were endorsed previously with 9 high protocols, 89 medium, and 12 low. Taking an average of reported accruals for the retrospective scoring categories, it was seen that high scoring protocols had accrued an average of 13 patients while low scoring protocols had accrued an average of an average of 2. This was compared to the prospective analysis of protocols scored after July of 2023 (Figure 2) where we see a median accrual of 1 patient (range of 0-9) over a median of 7 months.

Figure 1

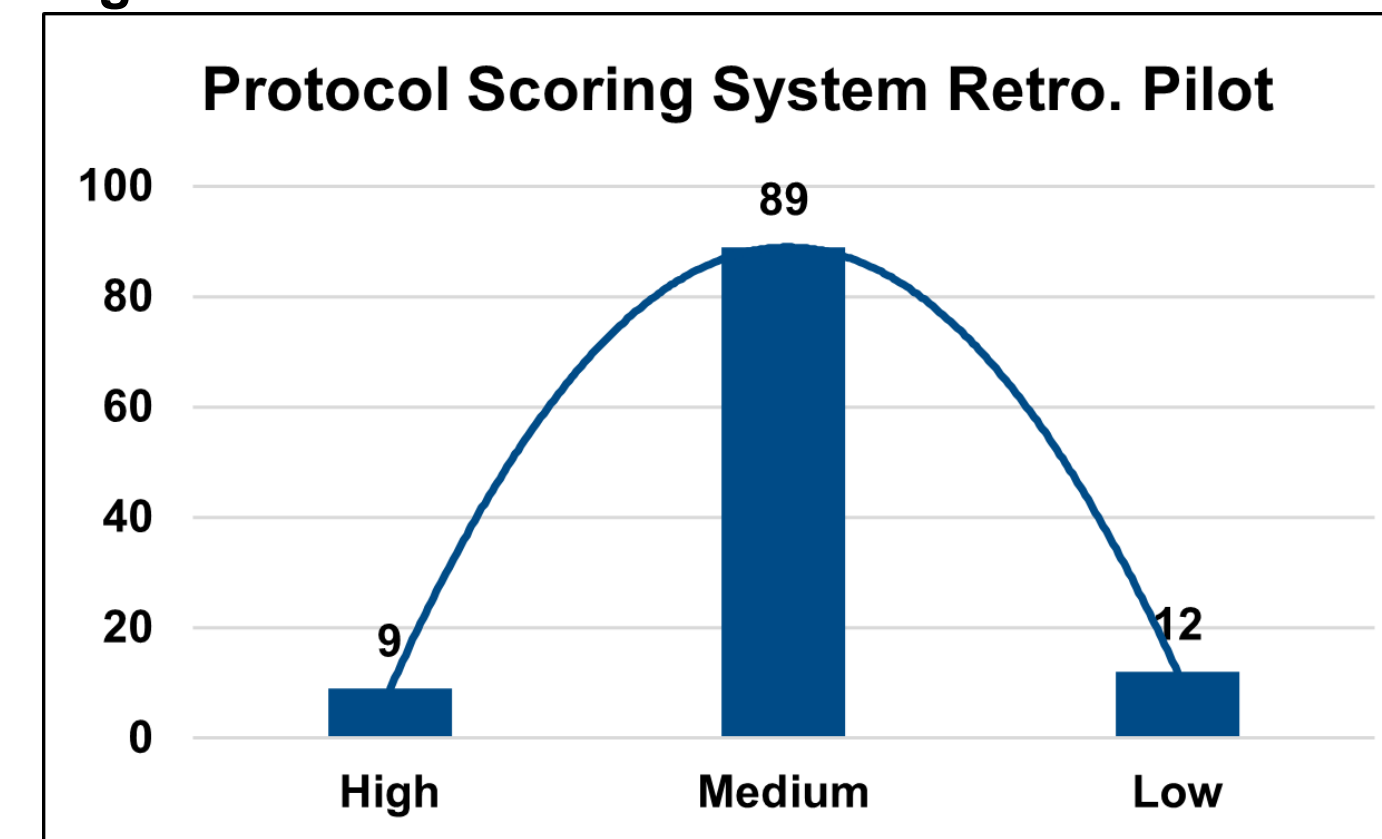
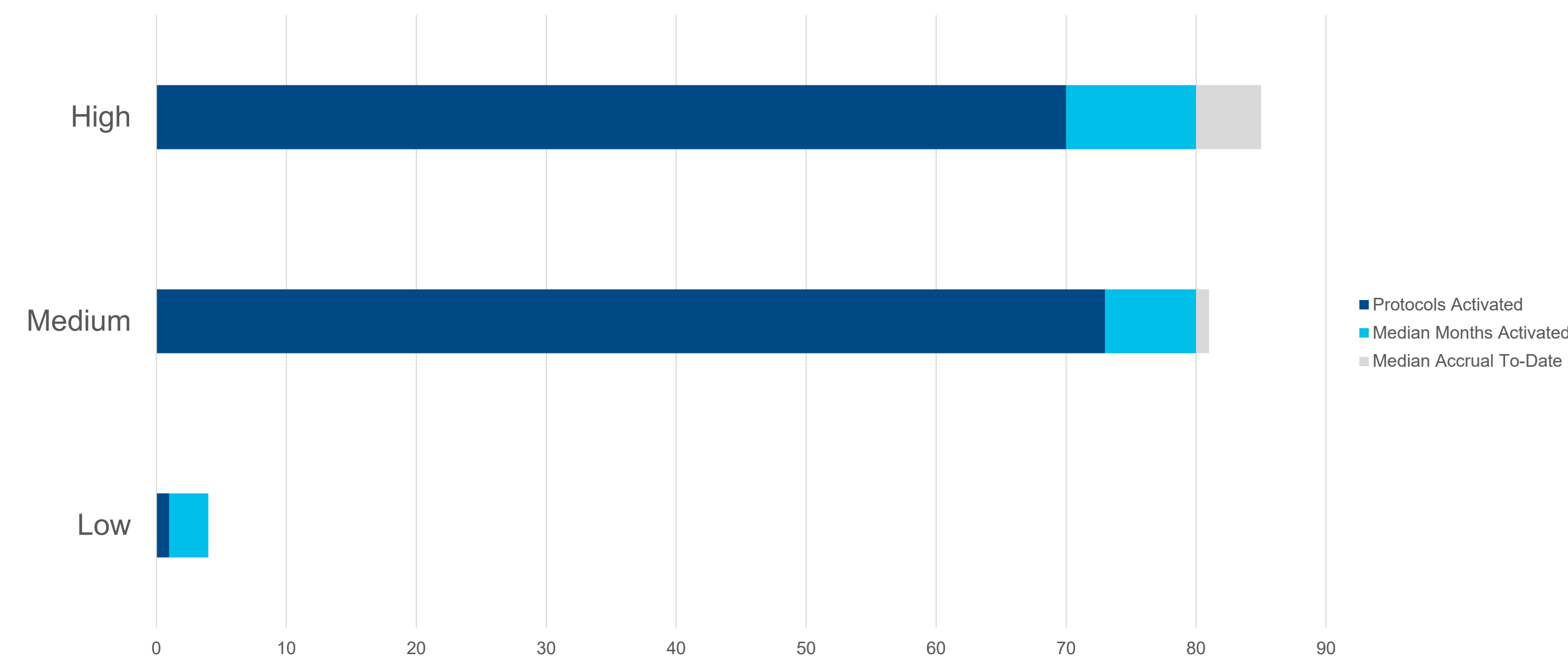
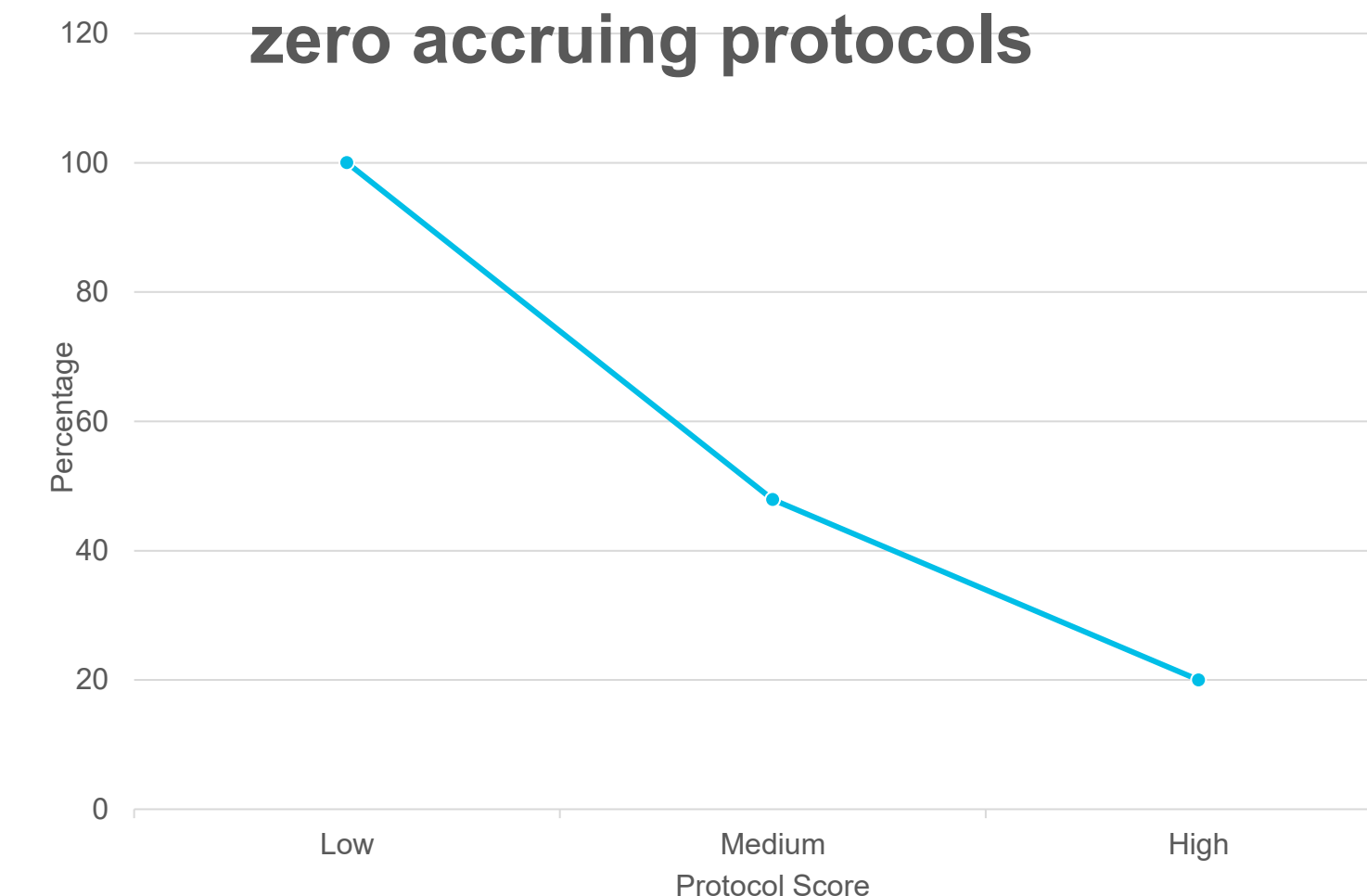


Figure 2: Prospective Protocol Scoring Analysis



for medium scoring protocols. High scoring protocols demonstrated a median accrual of 5 patients (range of 0-1837) over a median of 10 months. Further analysis (Figure 3) shows that the percentage of protocols with 0 accrual at the time of analysis were 100% for low, 47.9% for medium, and 20% for high scoring protocols. For protocols that had been activated for 1 year or more (21 medium and 17 high scoring protocols) at the time of analysis promised annual accrual was compared to actual accrual. Medium scoring protocols accrued a median of 40% of the promised accrual while high scoring protocols accrued a median of 70% of the promised accrual.

Figure 3: Prospective Analysis of zero accruing protocols



Discussion

These results demonstrate that disease teams are prioritizing the endorsement of medium and high scoring protocols over low scoring protocols. The previous bell curve of endorsed protocols has completely shifted to an almost even distribution between medium and high scoring protocols. High scoring protocols are activating faster as evidenced by the longer median to-date months of activation confirming the enforcement of the PRMS score prioritization during activation. Low scoring protocols could not be fully analyzed for accrual potential as only 1 low scoring protocol had been activated for only 3 months at the time of analysis with no accrual. Medium and high scoring protocols were activated at a comparable rate with high scoring protocols recording 5 times the amount of accrual.

Conclusion

Incorporation of the UCDCCC strategic plan into the PRMS protocol prioritization guide has predicted the protocol's ability for successful enrollment.

Future Goals

With the demonstrated proof of concept for thoughtful curation of a scoring rubric can implement portfolio changes across strategic plan goals we have the following future goals:

- Perform analysis on the four other scoring rubric categories to see if the predictive pattern remains true
- Utilize all data from prospective analysis to further refine the scoring rubric
- Continue to make iterative changes to the UCDCCC PRMS Scoring Rubric based upon strategic goal updates/changes