Gamification Toolbox—Sharing Gamification Ideas, Suggestions and Instructions With Others in the Clinical and Translational Science Workforce

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Introduction

As part of the efforts of the Trial Innovation Network (TIN) to improve and innovate the conduct of clinical trials, members of the Johns Hopkins, Tufts, Duke, University of Utah, and Vanderbilt TIN Trial Innovation and Recruitment Centers have created this toolbox of gamification techniques for clinical trials. We hope by sharing these gamification ideas, suggestions, and instructions, you might use gamification as a tool of engagement in your next trial or with others in the clinical and translational science workforce.

Purpose

This instructional tool will assist study PIs, clinical coordinating centers (CCCs), and central study teams in creating and implementing games for improving engagement and overall performance at participating sites during the start-up and enrollment phases of clinical trials. Topics covered in this manual include basic game design philosophy, special considerations when applying game design to clinical trials, mechanics of scoring, and thoughts and ideas on recognition of the players and for making game themes fun and relevant. Examples of games are provided and highlight how the methods described in the manual have been used. In addition, you will find guidelines on how to use and modify the templates and resources described in the toolbox. Study teams are encouraged to be creative with the techniques and methods described herein. And remember, you are making a game after all, so have fun!

Study teams are encouraged to expand upon and be creative with the techniques and methods described herein. And remember, you are making a game after all, so have fun!

When to Consider a Game

Engagement and motivation are crucial elements to the successful conduct of various clinical trial activities. Many standard tasks can feel disconnected from the study itself, and productivity of trial teams can wane as a result. Therefore, gamifying activities can be a useful tool to revitalize both site teams and the coordinating center staff for the improvement of a trial as a whole. Gamification can be included in any phase of a clinical trial, as within each period there are activities that occur in quantified amounts and in recognizable, defined durations. Gamification can be used as a tool to better connect and engage coordinating center personnel and site teams in general or to focus on specific trial goals or tasks that might be subject to risk. Whether a game is simple or complex, recognizing the best tasks and activities to gamify is the backbone to creating a game that works for your trial and your needs.

Gaming During Start-up Periods

During a trial start-up, site teams have a litany of regulatory and organizational steps they must complete prior to enrollment activation. Such activities are often plagued by roadblocks and slow-moving processes, extending the time, effort, and cost of starting a trial. Games focused on activities that might otherwise be de-emphasized or are at risk of becoming lost in the work shuffle can aid in keeping trial tasks at the top of a site team's to-do list and thus keep the team on schedule. Also, start-up games are an ideal way to recognize

Whether your game is simple or complex, recognizing the best tasks and activities to gamify is the backbone to creating a game that works for your trial and your needs.

others at the start of something new, and celebrates site teams for completing regulatory and contractual approvals and readying the site to open to enrollments.

Gaming During Enrollment Periods

The successful conduct of a clinical trial hinges on four elements: subject recruitment, subject retention, performance of the protocol, and data quality. Each of these four elements has an impact on finishing a trial on time, within budget, or on maintaining participant safety and data integrity. Gamification can engage site teams with recognition and awards for meeting recruitment goals, converting recruitment opportunities into enrollments, following the protocol with the least deviations, entering timely, accurate data without error, or preventing subjects lost to follow up. Most trials are long and hard and games can keep your site teams engaged and motivated.

Methods and Components of Game-Building

In the building of your game, you can start by selecting which activities you wish to gamify. To deliver a fully-developed game based on clinical trial tasks, you will need to consider the following major components of a game: scope (how much to gamify), metrics (tracking and measuring), scoring, balance, engagement and motivation, communication of results, recognition, trust & rapport, and of course, your theme. This toolbox will help you incorporate these components and gamify site performance to enhance engagement of your trial teams.

Determine which activities you wish to highlight as measures of success and recognition for well - performing site teams.

Scope - Choosing What to Gamify

Selective vs. Comprehensive Activities

In building your game, you will want to select which metrics you wish to include. If you choose to incorporate as many trial activities as possible, you create a comprehensive game. The benefit of a comprehensive game is that it will reward site teams for doing well across *all* trial aspects (including study start-up, screening, enrollment, subject follow-up, etc.), rather than just a limited set of activities. However, when everything is gamified, some site teams might become overwhelmed or unfocused and the importance or uniqueness of a game could be lost. A game that considers every possible element might become indistinguishable from the normal conduct of a trial, and interest in the game could wane. On the other hand, creating too selective a list of activities could divert valuable attention from other equally important activities of the trial. Determine which activities you wish to highlight as measures of success and recognition for well-performing sites.

Game Balance

There are many activities that can be used to build a game, however the key is to choose activities that are essential to the success of your specific trial. For example, if your study has a particularly challenging consent process, including consent success rate as a performance measure (metric) is likely an important criterion to gamify. As another example, a schedule for outcomes assessments in a difficult-to-find patient population could be particularly intense, making this activity a good target for recognition by gamification. Or an intervention timing might be strictly scheduled (e.g., a brief window to give a dose of test article), with compliance paramount to the primary outcome of the trial. Every trial will present its own unique challenges.

Trial activities that are more difficult for study teams to execute can be valued as game elements more than simpler or effortless activities; so, consider each activity's value to your trial's success as you select which activities to gamify. Tables 1 and 2 in Appendix A offer examples of activities and accompanying metrics you can consider gamifying. How you choose to target and weight these metrics determines the balance of your game.

What is a Balanced Game and why does it matter?

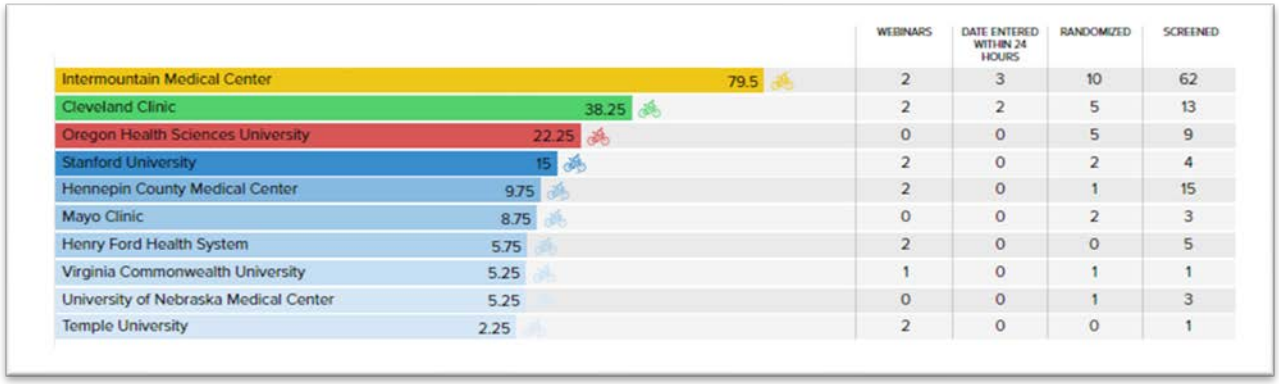
Game balance is an aspect of gaming that prevents one player or single strategy from unfairly overshadowing other players or strategies continuously throughout gameplay. There are many approaches to game balance, and the methods you choose will reflect the specific goals for your game. In a traditional game, the goal of game balance is to ensure that the best player wins every time. However, remember that the use of gaming in a clinical trial is used to enhance site engagement and performance. One might initially think that you would always want to reward the best performing site; but, lack of recognition for other sites might cause engagement to suffer. It is helpful to think through a variety of situations. What happens if one site has an insurmountable lead? What if sites have clear differences in enrollment capability? How can underdog sites be rewarded without making the frontrunner sites feel unfairly penalized for their good performance?

To begin, assign points to various activities (metrics) to competitively rank sites. Please note that while points might be the simplest method to combine various metrics into a unified criterion, games can be created without explicit point systems. How you balance those metrics both for fairness to your star performing team while you encourage trailing site teams is up to you. Keep in mind that the ultimate goal of a game is to improve engagement in your clinical trial. Remember to be creative and inclusive!

Keep in mind that the ultimate goal of a game is to improve engagement in your clinical trial. This toolbox provides various methods and considerations to achieve this, but remember to be creative!

Building Your Game into your Electronic Data Capture system (EDC)

Your ability to conduct a game will depend on a variety of metrics and require calculations to properly score the data. To avoid unnecessary data exporting and manual checks on the game's status, build as many components as possible into an automated system. For games conducted during the enrollment period, modifying your electronic data collection (EDC) system should be relatively simple. If possible, construct a scoreboard to quickly tabulate selected metrics and make it accessible to site teams to check on scores and standings in real time. You may also consider incorporating themes (more on this later) into the scoreboard (mountain climbing, stationary bike, etc.) to make it visually more appealing and easier to interpret (Fig. 1).



		WEBINARS	DATE ENTERED WITHIN 24 HOURS	RANDOMIZED	SCREENED
Intermountain Medical Center	79.5	2	3	10	62
Cleveland Clinic	38.25	2	2	5	13
Oregon Health Sciences University	22.25	0	0	5	9
Stanford University	15	2	0	2	4
Hennepin County Medical Center	9.75	2	0	1	15
Mayo Clinic	8.75	0	0	2	3
Henry Ford Health System	5.75	2	0	0	5
Virginia Commonwealth University	5.25	1	0	1	1
University of Nebraska Medical Center	5.25	0	0	1	3
Temple University	2.25	2	0	0	1

Figure 1. An attractive and easy to follow EDC scoreboard example from the VICTAS trial showing relevant metrics and scores. In this trial, scoring was based on webinar attendance, data quality, and recruitment.

As the EDC is most likely not functional for start-up activities, you could utilize an electronic Trial Management System (eTMS) to collect important benchmark dates while sites are onboarding. While this likely cannot be modified in the same way as an EDC, the metrics collected therein can be used to support your game. Before you begin game construction, make sure you know the capabilities of your EDC or study management systems. Work with your vendor-developers or staff developers (or other relevant technical assistance) to explore what you can implement on your platform(s). The complexity of your game will depend on what is feasible for your team to maintain and deploy over the life of a trial.

If game elements cannot be built directly into an EDC or eTMS, then consider what activity metrics will be most easily accessible to be gamified. What metric reports can you get from your data source to support your game with minimal burden? Consider how frequently you want game scores or results to be updated and how results will be disseminated to the sites. Will there be regular site calls or webinars where scores/results/accolades will be highlighted? If an EDC dashboard is unavailable, will results appear on a study website instead and if so, how often will that be updated? Be sure to use whatever standard site communication methods present in your trial to display the results of your game.

< Please proceed to the next section to learn about scoring methods>

Scoring

Deciding the appropriate activities to gamify (metrics) is your first challenge in creating a game. Next is the scoring system. Understanding the possible hurdles or difficulties in your trial operations will help you create an effective scoring system. Choosing metrics that cover the four major areas that determine the quality of a trial (recruitment, retention, protocol performance, and data quality) are a good place to start.

> EXAMPLE: A trial with a long follow-up period is prone to subjects who drop out or are lost to follow-up. There are six follow-up visits over a 2-year period. Enrolling a subject is assigned 2 points. In addition, each successful follow-up visit is given a value of 1 point. Each subject who completes the entire follow up period is now worth 8 points for the study team. Two of the four major performance areas are rewarded.

Metric Scoring Methods and Equations

There are several methods for scoring the components of a game. Each one has its own benefits; you can decide if one works well for your trial, or you can select a different method.

Method 1: Simple Weighted Metric

Score = Metric*Weight

For most metrics, you can measure a discrete number of event occurrences, then apply a given weight in order to scale the metric to be worth an appropriate number of points within the game. Weight is defined as any arbitrary multiplier applied to data to achieve a score or score component. This method is straightforward and works best for metrics such as screened or enrolled patients and completed outcomes visits. In the simple-weighted metric example above, a trial required intensive screening

Simple Weighted Metric Example

SITE	*ENROLLED*	*SCREENED*	*POINTS/ENROLLMENT*	*POINTS/SCREEN*	*TOTAL*
A	*1*	*20*	*4*	*0.25*	*9*
B	*3*	*4*	*4*	*0.25*	*13*

*Site A and B screen and enroll a different number of patients. Shown is an example of how each would score with the given weighting. Site A screens 20 patients and enrolls 1, giving the site 9 points for screening and enrollment (1*4 + 20*.25 = 9). Site B screens only 4 patients, but enrolls 3, scoring 13 points (3*4 + 4*.25 = 13)*

around narrow inclusion and exclusion criteria. The game builders assigned screening efforts a weight of .25, and enrollment successes a weight of 4. Every screened patient counts towards the total point count, but the team with the more efficient conversion rate (from successful screened to a successful enrollment), earns more points. This type of scoring rewards effectiveness as well as sheer numbers.

Method 2: Time-Based Metric

Score = Metric + (Days Early or Late*Weight)

For metrics involving specific timeframes with deadlines, i.e., when an activity or study event needs to be completed, it is likely that the completion date will occur before or after the specified deadline. In these situations, a point bonus or deduction can be calculated into the completion timeliness scoring, even to the degree of how early or late the activity was completed. This method of scoring is best

applied to relatively sparse or unique events that can be assigned to a reasonable but ambitious goal, such as the time taken for regulatory documents to be on file or contract execution (seethe time-based metric example below). In these cases, a base score can be applied to the expected completion date, then points earned are modified at completion by the number of days before (bonus points) or after (deducted points) the expected date. This type of scoring rewards getting the task done and additionally recognizes those who accomplish the task more effectively. Again, the site contract negotiation process is a good target for this type of scoring: the goal is set for contract negotiation and execution and measured as the time between a contract being received by a site to the time of partial execution at the site. Do not use this type of scoring to incentivize participant-related activities, as completing patient visit early could be detrimental to a participant or data integrity.

For this metric type, it may be necessary to implement an upper and lower bound to either the number

Time-Based Metric Example

SITE	*GOAL CONTRACT NEGOTIATION DURATION*	*ACTUAL DURATION*	*POINTS FOR TASK COMPLETE*	*POINTS PER DAY EARLY/LATE*	*TOTAL*
A	*49*	*51*	*10*	*0.5*	*9*
B	*49*	*41*	*10*	*0.5*	*14*

*Site A and B complete their contract negotiation processes at different speeds. For this example, an expectation of 49 days is selected as the deadline for a site to complete a partially executed contract. The expected date is given a weight of 10 points, with a bonus or penalty of +0.5 points per day early or -0.5 per day late. Site A completes the partially executed contract in 51 days, earning 9 points for this task during start-up (10 – (2*0.5)). Site B completes the task 8 days early, earning 14 points (10 + (8*0.5)).*

of days the weight will apply or the final points a site could earn on any given task. In the above example, suppose site A's contract negotiations happen much slower than the goal, and instead completes in 103 days. While this is not uncommon, it is certainly not ideal. By the formula given above, the site would score 10-(54*0.5) for a total of -17 points. A lower bound, in this case, prevents a single poor metric from invalidating other potential successes at a site. Conversely, if a site completes a given task much faster than expected, an upper bound prevents a single metric from catapulting a site team on to win when many of its other metrics might not be as stellar. Whether you choose to limit the number of days a weight can apply, or bound the possible scores for any given metric, consistency in application is recommended to avoid creating too convoluted a system.

Method 3: Percent-Based Metric

*Score = (number of events occurring within desired timeframe/total events)*Weight*

Continuous events that occur in significant number and must be well-timed should be expressed as a weight applied to a percentage of those events that occur within the goal timeframe. The most notable example of this type of metric is data entry timeliness. In contrast to large relatively rare events, data elements are numerous and total counts can vary per subject. Scoring on a per-data-element basis would be impractical and incredibly difficult to properly balance. To simplify this, a weight can be applied to the percentage of needed data elements entered within a certain number of days of a given event. Such metrics are normalized to the total number of events of that type that occur. This makes them especially useful to score the quality of a process that might occur at different frequencies across

sites or even across subjects. Rounding is typically necessary when assigning points to this type of metric, as ratios of event frequency rarely result in manageable numbers for a scoring system.

Balancing Metrics

Percent-Based Metric Example

SITE	TOTAL # OF VISITS	VISITS ENTERED WITHIN 48 HOURS	PERCENT COMPLETION	POINTS FOR 100%	TOTAL (ROUNDED)
A	*45*	*41*	*91.11*	*10*	*9*
B	*102*	*73*	*70.19*	*10*	*7*

*Sites A and B have differing rates of data entry: site A has fewer outcomes visits but is better able to stay on top of data entry. For this example, the expected goal is completed data entry within 48 hours of a study visit and is worth up to 10 points in the trial's game. Site A completes 41 of 45 data fields on a subject's case report form within 48 hours, and so scores 9 points for this metric (41/45 * 10 = 9.111). Site B, by contrast, has more patients, and therefore more data entry visits to enter. However, this added entry has caused a decreased rate at which they are able to enter data within the 48-hour goal, completing 73/102 visits within 48 hours and earning 7 points (73/104 *10).*

Except in very selective games, no single metric should influence the score of the game; sites should excel across most or all metrics to win. A winning site (or sites) should not be able to win by a single score (such as enrollments) while ignoring scores from other categories (such as timely data entry). Equally, no activity should be so insignificant to the overall site score that a winning site can ignore it and still win.

Scaling vs. Non-Scaling Metrics

CASE IN POINT: A site has twice the enrollments as the next closest site, and seems to screen every patient that comes in the door. But every enrollment has a significant delay in data entry, and monitoring queries are not resolved promptly, and outcomes visits occur close to or outside the protocol collection window. In a well-designed game, this site should not be able to win by their large enrollment metric alone. Balanced correctly, a site with fewer enrollments, but impeccable data entry and patient retention should stand an excellent chance of coming out ahead

Another component of proper balance is to use a mix of scaling and non-scaling metrics in your overall scoring methods. A scaling metric is one that always increases with more events (screens, enrollments, etc.). A non-scaling metric has a maximum possible value no matter how many instances occur (100% queries answered within X number of days). Scaling metrics can favor sites with certain characteristics over others, while non-scaling metrics are achievable equally across all sites.

GAME BALANCE CASE STUDY

A feasibility survey confirms that study sites will have very different study populations. Although all sites are notable regional treatment centers, some sites will be able to screen significantly larger numbers of patients due to their location, and would likely score more points for recruitment activities. The rest of the sites selected indicated fully-dedicated research coordinators, signifying an environment for quick and efficient complete data entry and query resolution as enrollments occur. Both activities are important to the success of the trial.

HOW WOULD YOU FIND BALANCE ACROSS THESE VERY DIFFERENT ACTIVITIES?

You would structure points for the screening/enrollments, using the *simple weighted scoring* (method 1) above, and the *percent-based metric scoring* (method 3) for the data entry points. You could also add a query resolution score using the same *percent-based metric scoring* method. As the trial progresses, higher enrolling sites will accrue better recruitment scores, but offsetting with non-scaling metrics gives more sites a chance to compete and makes the game more interesting.

The scoring rules are then as follows:

- .25 points per screened patient
- 4 points per enrollment
- 10 points for 100% data entry within 48 hours
- 10 points for 100% query resolution within 48 hours

Using the calculations displayed in the two tables below, metrics are converted to Points**

Game Point Totals:

- High enrolling sites (A) score: 23 (22.84 rounded)
- Low enrolling/High data quality sites (B) score: 24 (23.97 rounded)

Calculations for Balancing and Converting to Game Point Totals

Raw Metrics from the EDC:

SITE	*SCREENS*	*RANDOMIZATIONS*	*DATA FIELDS*	*DATA FIELDS COMPLETED WITHIN 48 HOURS*	*QUERIES ISSUED*	*QUERIES RESOLVED WITHIN 48 HOURS*
A	17	2	70	36	11	6
B	10	1	35	32	6	5

Converted to Game Points**

SITE	*SCREENS*	*RANDOMIZATIONS*	*DATA FIELDS COMPLETED POINTS*	*QUERIES RESOLVED WITHIN 48 HOURS*
A	4.25	8	5.14	5.45
B	2.5	4	9.14	8.33

A CLOSE RACE…and an interesting one too!!!

Balance by utilizing teams and stages

In most trials, there is a naturally wide range of site performance. Some sites may not be able to keep up with the higher scoring sites, no matter how you balance the game scoring system. This could be due to lack of team coverage, personnel changes, administrative burdens, etc. When creating a game in these circumstances, it is helpful to choose a theme that groups multiple sites together as a team (e.g., boat races where multiple sites make up a single boat). The team should be balanced by the metric(s) most likely to cause an early imbalance (i.e., combine high enrolling with lower enrolling sites). Using another tactic, you can conduct a game in stages, recombining interim-stage winning teams with lower scoring teams and starting a new race. Even in individualized games, a close out award ceremony for early winners can end one race and a announce a new game, giving sites a second chance to win in the new game. This is especially encouraging to site teams that have experienced setbacks unrelated to the trial itself, such as a valued team member going on family leave.

Other "Mechanical" Scoring and Balancing Considerations:

Abusable Metrics

When designing your game, avoid abusable metrics. An abusable metric is one that by selectively controlling one's interaction with the game, you unfairly influence the point structure in your favor. For example, you may initially consider awarding points based on a screening-to-enrollment conversion ratio, thinking that sites that randomize a higher proportion of screened patients are doing a better job enrolling available patients. However in doing so, some sites may consider omitting screenings on the log to artificially inflate the score attached to this metric. While it's unlikely that a site team will manipulate the game in this way, it is nonetheless important to monitor for and avoid inadvertently incentivizing such behavior.

Incentivizing Site Team Behavior and Bonuses

You can utilize scoring elements to incentivize desired behaviors outside of the standard set of trial activities. You can incorporate bonus points to promote leadership and engagement with the coordinating center activities and other sites' teams. Such things include but are not limited to: credit for writing newsletter articles, attending trial-related webinars and/or giving presentations at webinars, submitting posters for annual meetings, presenting at local grand rounds, etc. Be creative with how you reward your site teams for their hard work and when they go above and beyond traditional trial responsibilities.

< Please proceed to the next section on selecting themes>

Themes

Themes encompass the entirety of the subject matter, visuals, and motifs that define the central metaphor of your game. The concept of a game is lost without a theme,. It should be developed early in the game-design process, as it can influence how a game is designed, built, and played. The theme is what will engage your players and provide the background and goals for the game. The theme should promote feelings of excitement and fun while playing; if it does not, then the game will not be effective (Kappen, D.L., and Nacke, L.E., 2013).

> …making it into a game is to create fun with a new system of measuring progress and the notion of recognition for reaching goals.

Providing context as to *why* a game is being played is an integral step in capturing a player's interest. Players want to know why they're playing a game. When gamifying in the workplace, there is already a reason why the work is being done—work goals. Making work goals into a game creates fun with a new system of measuring progress and the notion of recognition for reaching these goals. In clinical trials, the "why", or goal, is about treating patients and discovering new approaches to care for them. Games can engage and focus site teams on trial tasks, which in turn adds an additional layer of engagement to help get crucial trial tasks done. The theme is the first impression your game will make on the players, so pick one that is likely to engage players at the onset.

Flow

Ae theme's flow becomes intertwined with the flow of trial tasks and can enhance or hinder a team's motivation to play a game, when it is done right or not. Flow connects the lifecycle of a game—from the minute it begins to the end—and requires clear goals, progress and feedback (Zinger, 2014).

Goal Metrics and Rewards

Goal metrics and reward systems are elements that are important to include in the design of the theme. Rewards can be attributes like progress bars, a point system, levels reached, a collection of badges, or the postings on leaderboards. Attributes should relate to the game theme and operate as beneficial feedback, providing opportunities for your team members to fulfill their intrinsic need to feel competent

> CONSIDER THIS: In the day-to-day operation of your trial, you have designed how the protocol will be executed with a consistent flow in mind. Such considerations are important for site team performance. Steps to perform the protocol are clearly defined and in a sensical order (flow), from the initial identification of a potentially eligible study participant through the cycle of a patient's participation. What theme will you model, based on a common sport, challenge, tournament or contest and the flow of your protocol and required trial performance?

(Meckler, E. et. al, 2017) and accomplished. According to Kramer and Amabile, progress is one of, if not the most, important variable that impacts motivation and engagement (Amabile, T., & Kramer, S., 2011).

> CONSIDER THIS: Progress of clinical trials overall can be measured by metrics such as number of patients enrolled. The objective of gamifying the work to be done warrants a connection of the work to the game via the theme; and connecting game progress to enrollment accomplishments means more points are awarded to the most competent site teams. What theme elements will you use to award accomplishments?

Fun

When you take the time and effort to build games into clinical trials, you are motivated by a desire to find ways to both engage and focus teams to get the job done and to brighten the way the burdens of trial tasks are perceived. If you are having fun relating your trial tasks to a game, that enthusiasm will be communicated to your site teams and will enhance their engagement with the trial.

Rewards and Recognition

Games naturally go hand-in-hand with ceremonies and awards. While intrinsically motivating games reward an individual with interest and enjoyment, external rewards such as acknowledgement can be equally effective when they are designed to elicit a sense of competence and autonomy. Examples include long-lasting and displayable certificates, plaques, and trophies. Team building examples can include gift cards, educational luncheons hosted at the site, and educational grants (Fig. 2). Each of these examples elicit recognition of the work put in by site teams. Whether they are small-scale virtual points within the game or awards that publicly recognize achievements, the context must be carefully developed to maximize the beneficial effects of recognizing the work—ultimately increasing the motivation and satisfaction of the participating sites. Therefore, it is crucial you choose reward structures that are acceptable to your institution and institutional IRB. It is important for you to know your university and affiliate guidelines for researchers and staff to receive or disperse rewards of acknowledgement (not bonuses or incentives) for non-participant-related trial activities.

Figure 2. Recognition and awards are structured into the game as an element of enjoyment about team and internal accomplishments. Teams receive small awards of appreciation, and photos of the event are posted on the website and in newsletters.

Encouraging Continued Gameplay

When your site teams begin to play your new game, the novelty of it can be interesting enough to encourage use initially, but it will be important to encourage gameplay for the long-term. Features that encourage engagement, such as evaluative feedback (website leaderboards, two-way surveys), personalization of team accomplishments, and access to standings can make or break sustained interest in your game.

Evaluative feedback, along with visualizations of a player progress, can have a positive impact on continued game interest. One study (Burgers et. al, 2015) found that evaluative feedback had the strongest effect on increasing a player's likelihood of playing the game again. Phrases like "You completed the game rather quickly", or "You completed the game in a time that is below the average of people in your age group", was correlated with players wanting to continue playing the game long-term, while negative feedback prompted players to play the game again in the immediate future, but not long-term. Even if your game is not high-tech enough to be immediately interactive, coordinating center staff and leaders should deliver feedback regularly. Use whatever tools are at your disposal, from trial-wide notices on website leaderboards, webinars and newsletters showing the current standings, to special emails and thank-you letters personalized to individual teams or persons. Make specialized announcements for whole trial teams for outstanding performance in individual areas, and recognize individual outstanding members for their contributions to their site's performance in the game.

The difficulty level of a game has a significant impact on whether or not a player continues playing long-term (Sedig, K., et. al, 2015), although a game's ease of use does not necessarily indicate scoring points will be easy. Consider what aspects of your trial will be most difficult for your sites to achieve, and reward them accordingly. Your game's theme can highlight the most difficult tasks with the most impressive metaphors, from finishing a difficult turn in a race quickly to hitting a curveball for a homerun.

Finally, make sure your game does not add burdens to site teams. Most likely your game will be built using metrics already collected on your trial data platforms, the games will be tabulated and scored automatically at the coordinating center or in the data platform, and the site teams will be spectators of their own accomplishments achieved doing the day-to-day routines of conducting your clinical trial. Done well, you will have already balanced and weighted the game scoring system for those aspects of the trial that are the easiest and the most difficult for sites to achieve, whether they be securing institutional approvals, or enrolling a rare population or getting right a complex protocol. Sites should easily see the rewards and displays of recognition for as many tasks as you can create or name. Happy Theming!

< Please proceed to the next section on game examples>

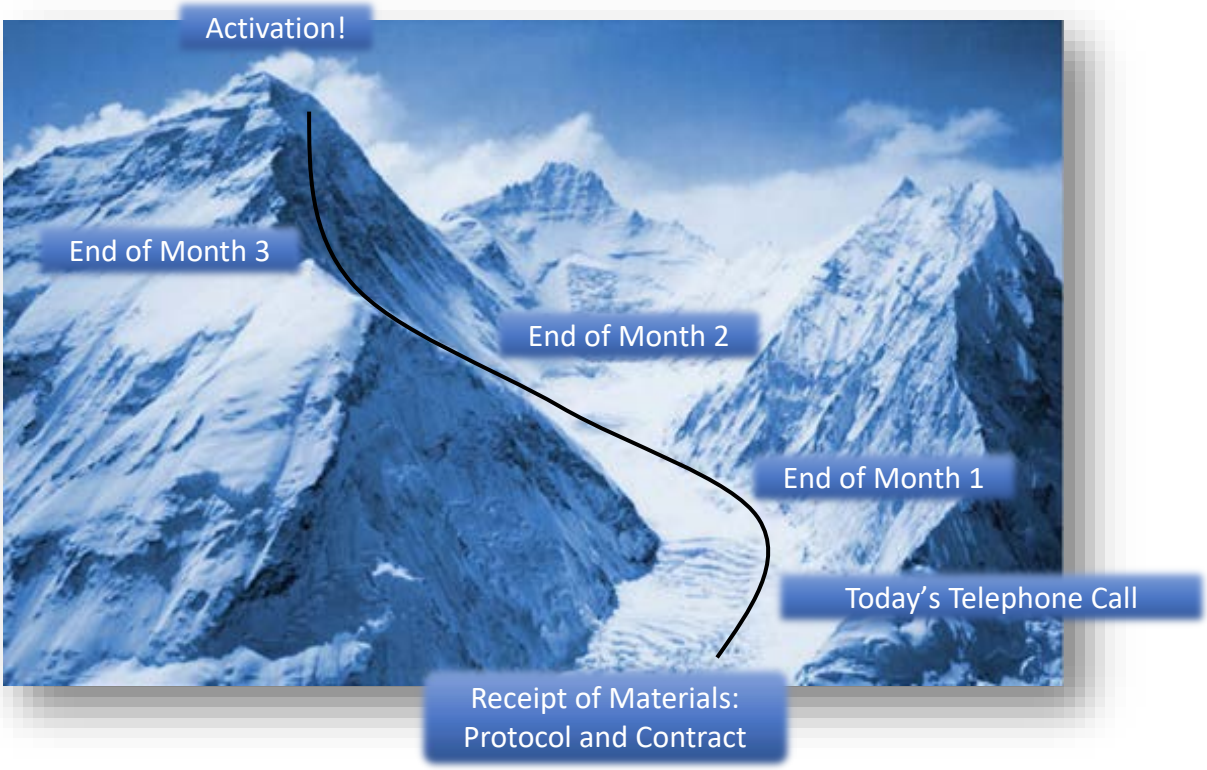
Examples of Gamification in Clinical Trials

The following examples have been used during the start-up and enrollment phases in multiple clinical trials. Please feel free to use these game themes for your trial or perhaps as an inspiration to create your own.

Mount Everest

Introduction and Theme

The Mount Everest game is designed for the clinical trial start-up phase. Just like scaling a mountain, there are many discrete steps and parallel challenges to quickly activate sites in a multicenter trial. But with perseverance and steady progress, the summit can be reached and the challenges overcome. A climb to the top of Mt. Everest has multiple base camps as you trek up to the summit, and the game stages start-up activities into three monthly "base camp" milestones. The theme functions well tracking activities, whether sites "leave base camp" at different times, as sites are frequently given the materials they need to begin the start-up process at different times, or in multiple groups.



Major Balance and Scoring Considerations

The following major design points are incorporated into the Mt. Everest game. While you will customize game specifics to your needs, you can use these design considerations as a starting point when constructing your own start-up game.

1. While activation is the end goal, there are common barriers to every activation timeline. Therefore, the game is designed to reward individual start-up tasks along the way. The final step of activation can be assigned a small point value for a finish under the timeline, but keep the

value small so as not to disadvantage otherwise well-performing site teams that might be delayed by tasks not in their direct control (e.g., a busy contract office).

2. Point totals express an overall *rate* of completion rather than measure which site team crosses the finish line first on the calendar. Because site teams receive needed start-up materials at different times (as climbers leave base camp at different times), each site is timed and scored according to its own start time.

3. Assign larger point values to major risk factors that are directly within the site team's control. The completion of the study team tasks, such as submitting and routing approvals, the collection of personnel-level regulatory documents, and completing training requirement, are emphasized. Assign smaller point values for institutional IRB or ORA deliverables.

4. Major tasks are given points according to the *time-based metric* method explained in the scoring section. To prevent any single task from having an outsized effect on a site's overall point total, bonus points given per day early or late are capped at 14 days. Tasks assigned a greater initial point value were assigned a correspondingly higher weight on the bonus/penalty points per day.

Mt. Everest time-based metric distribution and weights are in the table below.

Metric	Goal Duration	Base Points for Completion	Bonus Points per Day Late/Early
Protocol Available to Local Context Questionnaire (LCQ) First Draft	21	5	0.4
Protocol Available to Site Specific Consent Information (SSCI) First Draft	21	5	0.4
Contract Available to Partially Executed	42	10	0.7
Regulatory Document Templates sent to Delegation Log Circulation	35	5	0.4
Delegation Log Circulation to Finalization	14	5	0.4
Regulatory Document Templates sent to Site Level Regulatory Documentation Completion	56	15	0.9
Regulatory Document Templates sent to Personnel Regulatory Documentation Completion	56	10	0.7
Training Available to Training Completion	77	10	0.7
Total Site Activation Duration	90	1	0.2
*Weekly Meeting Attendance		1 per meeting attended	N/A
ǂMonthly Webinar Attendance		1 per webinar	N/A

*ǂAn Accelerated Start-up Program can be used in conjunction with this game design, as it features weekly check-in meetings with the coordinating center and monthly educational webinars covering important start-up topics. A single point can be rewarded for each meeting and webinar attended.

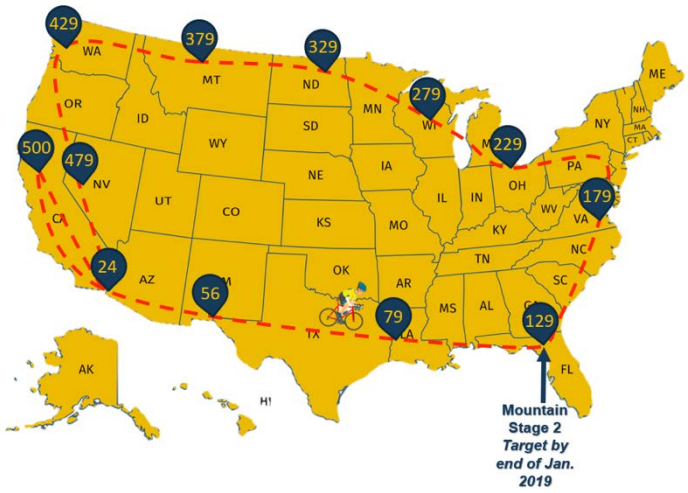
Other Major Features

When coordinating center and/or site teams enter dates for completed start-up activities into the EDC or eTMF as part of their weekly start-up routines, displays of calculated scores are available in real time with minimal added effort. Additional coordinating center effort will be required to create graphics, present standings and host awards at monthly webinars or through other means of communication. No effort is required of the site teams, except to visit the display sites and attend regularly scheduled trainings and meetings. Site teams play the game simply by performing their trial responsibilities.

Tour De France (AKA, Your Trial Name)

Introduction and Theme

This game is designed to be implemented during the enrollment period of a trial and can be easily programmed within the REDCap system or a similar EDC. The game is a selective game, focusing on a few key metrics. If you are a fan of professional cycling and the Tour de France, you can adapt it to show monthly enrollment progress by cycling across a map in a race to recruit subjects towards your trial's enrollment goal.



Major Balance Considerations

As with most actively enrolling trial games, a balance between scaling and non-scaling metrics is used to ensure that sites with an advantage due to larger patient volumes don't have an outsized advantage in the game. In this game, the scaling metrics for enrollments and screens are balanced against data entry (a percentage-based metric), and webinar attendance (a metric that occurs in equal number for all sites).

In addition to the overall cross-country cycling event, there are episodic "Mountain Stages" programmed in during certain trial months, when *additional* bonus points could be earned by being the leader in any given category for that month. These bonuses should be targeted at historically difficult enrollment months. These special sprints encourage enrollments overall and give site teams an opportunity to catch the leaders. For example, "Mountain Stage" points can be awarded for screening, randomization, and data entry, with 3 bonus points given for first, 2 for second, and 1 point for third per category.

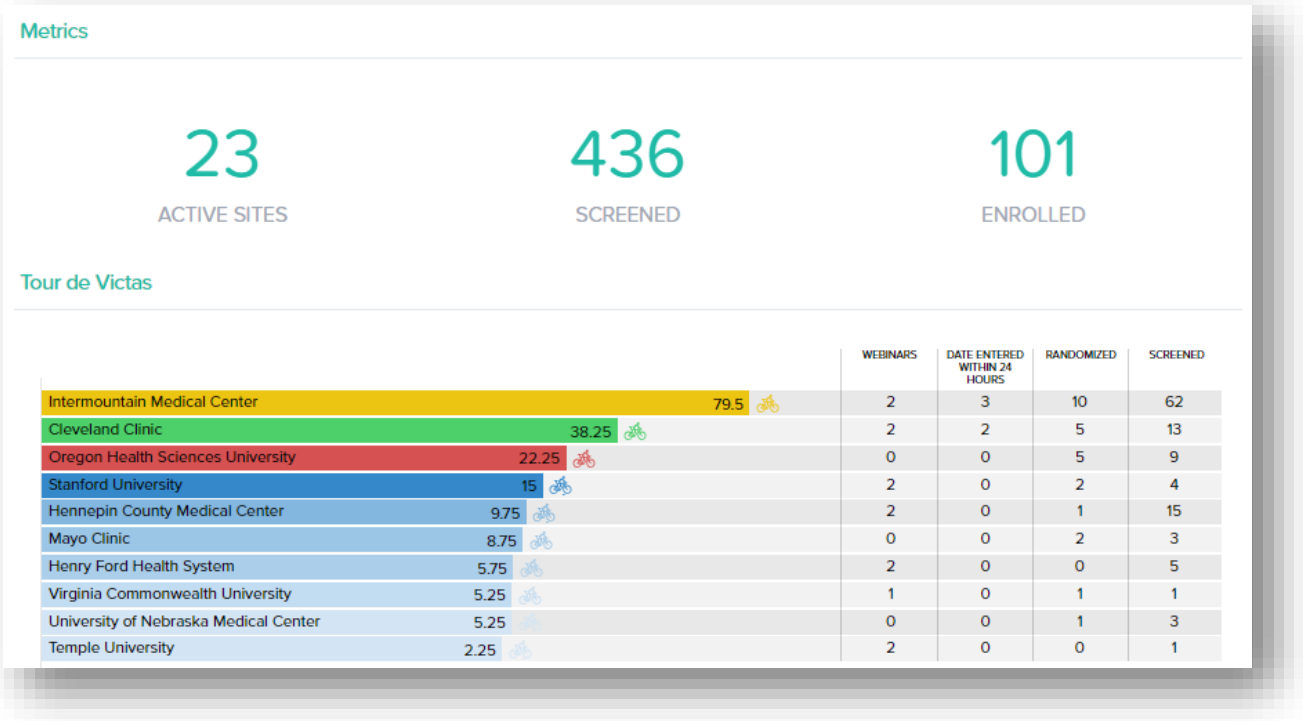
Scoring

Sample point values of the scored metrics are given by the table below.

Metric	Weight
Screening	.25 points per screen
Randomization	4 points per randomization
Data Entry: % Of Data Entered within 24 hours of a visit	Normalized to 10 points for 100%
Webinars	1 point per monthly webinar attended 5 Points for presenting

Other Major Features

Below is a sample of a visually appealing scoreboard for the game that can be easily presented on the front page of a trial's EDC or website.



< Please proceed to the next section on engaging site teams>

Engagement and Motivation

Your intended players will be site coordinators, PIs, and other study staff responsible for patient enrollment and data entry during a clinical trial. While there is no guarantee that gamification will result in a faster, more productive trial, there are other benefits to using games. When sites feel disengaged or disheartened, games can be used to encourage communication and a renewed sense of commitment to the trial goals. Turn the burdens of a trial into challenges and use small goals that can be unlocked or achieved through the design of your game. In this way, gamification changes the way in which burdens are perceived. Gaming creates opportunities for recognition, friendly competition, and fun, and your game building efforts can make a difference in how your site teams perceive your trial, in spite of the burdens they face to keep it going.

Intrinsic vs. Extrinsic Motivation

A basic understanding how individual game design elements motivate, energize and engage players can help you as the game's designer, provide an engaging and enjoyable add-on to the conduct of a clinical trial. (See Motivation sidebar.)

There are two types of motivation as defined by self-determination theory—intrinsic motivation and extrinsic motivation. Gamification in general typically incorporates external outcomes that recognize and reward outstanding performance (extrinsic motivation). Gamification can also encourage the pursuit of an activity because participation in a game is inherently enjoyable/interesting (intrinsic motivation). This could be anything from creating a sense of friendly competitiveness between colleagues to fostering an attitude that playing the game will lead to improved trial metrics across the trial, leading to better clinical research. Both types of motivation can promote improvement in performance, yet only the intrinsic aspect has been linked to enhancement of greater values, such as extent and quality of effort put into tasks.

Intrinsic motivation should be emphasized in your game, as the gaming experience should go beyond external gain and optimally connect the site teams to the idea of finding satisfaction internally by *participating*. Intrinsic motivation is nurtured by making sure friendly aspects are highlighted during displays of standings, and ensuring that rules and systems are easy to understand. Interesting and relevant themes and interactions with the players also create a more enjoyable experience.

MOTIVATION

Motivation is a broad topic, and our understanding of motivation in games continues to evolve. This section on motivation through games as an engagement platform is intended only as a reminder that engagement and motivation are tightly related to gamification. When you begin to design and build your game, we encourage you to read more about motivation in games. Recommended reading:

S. Deterding (2011) Situated motivational affordances of game elements: a conceptual mode

Ryan R. M., Deci E. L. (2000). Self-determination theory and the facilitation of intrinsic motivation, social development, and wellbeing. Am. Psychol. 55 68–78

Deci & Ryan (2000) *Intrinsic and Extrinsic Motivations: Classic Definitions and New Directions*.)

Cerasoli et al. (2014) Intrinsic motivation and extrinsic incentives jointly predict performance: a 40-year meta-analysis.

Trust & Rapport

In addition to engagement and encouragement, a game can send the message that you and your leadership want site teams to succeed and also have fun. This can promote feelings of trust and rapport between the coordinating staff and trial sites. Furthermore, it is a chance to talk about performance in a way that allows each site team to track progress toward its own predetermined goals as well as the overall goals of the trial and the other site teams. It

gives trial leadership the opportunity to praise performance and share what goals are possible with those lagging behind. Everyone gets to see the impact they're having on the trial as a whole, thus creating a more collaborative community. Games can promote transparency and allow site teams to experience real-time feedback about their impact on the success of the trial.

Everyone gets to see the impact they're having on the trial as a whole, thus creating a more collaborative community.

These feelings of partnership and collaboration are important. When coordinating center staff focus on rapport through engagement and advocacy, with or without gaming, the relationship with an enrolling team is strengthened and a partnership is formed, building a foundation for the coordinating center and site teams to develop strategies together, potentially resulting in improved trial performance. This is the foundation for a game as an extension of the collaborative coordinating center-enrolling team partnership.

Without a foundation of partnership and trust, site teams may find little value in playing the game (e.g., a team might find little value participating in the trial, or in building a relationship with the coordinating center). Some teams may even ignore the game and in turn, avoid interactions with the coordinating center. However, successful coordinating center staff will not give up but rather work to gain trust and rapport. Above all, strive to help each site recognize the team relationship is worthwhile, and the game plays an important role in supporting the partnership.

< Please proceed to the Toolbox Appendices>

Appendix A: Possible Metrics to Gamify

Table A1. *List of possible start-up period metrics and suggested methods to calculate them. The weight portion of the metric is a simple arbitrary multiplier used to balance the impact of these metrics in your game.*

A1. START-UP PERIOD

Metric	Metric Type	Sample Calculation	Comments
IRB			
Time to IRB Submission	Time-Based Target	Completion Weight + (Goal Duration - (Date of IRB Submission – Date of Protocol Receipt)* Weight)	Start-up Metrics should be graded based upon completion of a task in relation to a duration-based goal.
Time to single IRB Cede Decision	Time-Based Target	Completion Weight + (Goal Duration - (Date of Cede Decision – Date of Cede First Contact)* Weight)	
Contract			
Time to Contract Redlines	Time-Based Target	Completion Weight + (Goal Duration - (Date of Redlines returned to central ORA – Date of Subaward Release)* Weight)	
Time to Contract Partial Execution	Time-Based Target	Completion Weight + (Goal Duration - (Date of Partial Execution – Date of Subaward Release)* Weight)	Partial Execution is typically a better metric than full execution, as full execution can depend upon other processes like IRB approval.
Regulatory and Training			
Time to Delegation Log Completion	Time-Based Target	Completion Weight + (Goal Duration - (Date of Log Completion – Date of DOR template Receipt)* Weight)	
Time to All Training Completion	Time-Based Target	Completion Weight + (Goal Duration - (Date of Training Completion – Date of Training Available)* Weight)	
Overall Activation Duration	Time-Based Target	Completion Weight + (Goal Duration - (Date of Activation – Date of Protocol Available)* Weight)	

Table A2*. List of possible enrollment period metrics and suggested methods to calculate them. The weight portion of the metric is a simple arbitrary multiplier used to balance the impact of these metrics in your game.*

A2. ENROLLMENT PERIOD

Metric	Metric Type	Sample Calculation	Comments
Recruitment			
Number of Screens	Simple	#of Screens *Weight	
Number of Enrollments	Simple	#of Enrollments *Weight	
Screen % of Census	Percent-Based	(#of Screens / #of Patients seen with the condition of interest) *Weight	
Enrollment % of Census	Percent-Based	(#of Enrollments / #of Patients seen with the condition of interest) *Weight	
Retention / Protocol			
Successful Outcomes Visits (Scaling)	Simple	#of Outcomes Visits within Window * Weight	
Successful Outcomes Visits (Non-Scaling)	Percent-Based	(#of Outcomes Visits within Window / Total #of Visits)*Weight	
Subject Adherence to Protocol (Scaling)	Simple	#of Subject dependent entry events * Weight	This could be medication adherence, patient reported outcomes, etc.
Subject Adherence to Protocol (Non-Scaling)	Percent-Based	(#of Subject Dependent Entry Events / Total Number of Possible Events)* Weight	
Number of Protocol Deviations	Simple	#of Protocol Deviations * Weight	The weight in this case is negative and should be small. Be sparing with penalties in this area, as some deviations may be unavoidable for subject safety. This should be an incentive to follow the protocol as closely as possible.
Data Quality			
Visits Entered within 7 Days	Percent-Based	(#of Visits Entered within 7 days of occurring / Total Entered Visits) *Weight	
Queries Answered within 7 Days	Percent-Based	(#of Visits Entered within 7 days of occurring / Total Entered Visits) *Weight	

Appendix B: Glossary

Avatar	A personalized graphical illustration that represents the player of a game; this could be the 3D representation of a person, a 2D icon, etc.
Game Balance	An aspect of gaming that prevents a player or strategy from unfairly overshadowing other players or strategies throughout gameplay.
Burden	In a clinical trial, perception that the time and motion required to conduct a trial creates a negative force on research team beneficence and satisfaction
Game flow	The entirety of a game's experience, including user control over a game, audio/visual components, game play, etc.
Gamification	The application of typical elements of game playing (e.g., point scoring, competition with others, and rules of play) to other areas of activity to produce desired effects.
Gaming	The action or practice of playing a game
Leaderboard	A board or list showing the names and scores of those who are participating in a game. The list can be all-inclusive, or could choose to highlight those who are doing the best in the game (i.e. a top ten leaderboard would be a list of only the ten highest performers in a game).
Metrics	Any measurable and quantifiable element collected during a clinical trial that can be targeted to score a clinical trial game
Abusable	Any metric for which optimization can potentially involve intentionally manipulating one's conduct of the trial in an adverse way
Non-scaling	A metric whose maximum value is capped, such as a ratio
Scaling	A metric that has no maximum value, such as a straight count of screens or enrollments
Time-based target	A metric generated by measuring how close to a goal date or goal duration an event occurred
Weighted	A metric generated by counting a discrete event and applying a multiplier
Motivation, Extrinsic	Prompts the doing (or avoidance) of something because of an external reward or punishment.
Motivation, Intrinsic	An innate drive to do something (or the pursuit of activities that are rewarding in and of themselves).
Mount Everest game	Elements of trial tasks were gamified to simulate Mt. Everest basecamps and its summit as milestones in a climb to the summit that represented completion of all tasks
Percent-based metric	A metric generated by measuring the percentage of events meeting a given criteria
Rowing Game	Elements of trial tasks were gamified to simulate a rowing competition in a race to a finish line that represented which boat traveled the most miles.
Themes	The subject matter around which a game is built.
Tour de VICTAS	Elements of trial tasks were gamified to simulate a cycling race to a finish line that represented monthly task completion status. Based on the Tour de France cycling event.
Trust & Rapport	In gamification constructs, the gamification of trial tasks as a positive force in building enjoyable interactions and connections (rapport) and confidence in partnerships (trust) between sponsors and research teams.
Weight	Any arbitrary multiplier applied to a metric for the purpose of scoring balance