Grants: Success Factors and Differentiators – From Wow to Pow

Competition for funding is fierce, and only a minority of proposals receive support. For some, the chances of success can be close to zero. Funding for patient-oriented research in particular lags behind that allocated for basic science research. The skill of grant writing is therefore essential to your average clinical researcher.

The secret of creating appropriate applications whether the funding you are seeking is intended to support a biotech venture, multicentre consortium plan or investigational project, is based on fulfilling long-recognised criteria that define the 'why' and 'how' of your application. But times are changing and so are requirements, putting the pressure on those writing proposals to up their game. We provide here some key learnings from the Niche medical writing team, who have been writing grant applications for the academic and industrial partnerships since 1998.

Before you start

Grant writing is an arduous process and often feels harder than actually doing the work you are looking to fund.

- You will need to do more than just presenting a technically sound idea.

- You also need to clearly demonstrate how funding your idea will benefit the grantor

- Many funding applications fail, not because the funding body does not like the idea, but because the application is poorly prepared

- Do your research before you even start thinking about writing. Speak to funders directly where that option is available.

- Determine whether the odds of receiving funding warrant the effort it will take to prepare a competitive proposal

Prepare to succeed

Effectively a grant submission is a sales document make it clear to the funder what they are going to get in return.

State clearly what are you doing and why are you doing it. Present the knowledge gap that needs addressing and underline the uniqueness of your approach.

Present a clear and detailed plan of what you intend to do and how you intend to do it.

Fit expenditure to the project delivery timeframe. Fully break down the costs and justify them.

As with any piece of work you will be judged on the overall quality of your submission – make it good. A thorough proofread is worthwhile.

A good idea is no guarantee of success. Have a strategy for when your application fails.

Background

Grant writing is an arduous process and often feels harder than actually doing the work you are looking to fund [1]. With securing funding becoming increasingly more difficult, grant-writing know-how is more important than ever. You will need to do more than just presenting a technically sound idea. You also need to clearly demonstrate how funding your idea will benefit the grantor. Effectively a grant submission is a sales document. What does the grantor get in return?

When considering your proposal, you will most likely have an idea of what you want to achieve. But this idea may not be fully formed and so you need to give full consideration as to how you are going to get from A to B. It is tempting to write creatively and expressively in an effort not to bore the reviewer but this almost always the wrong choice for competitive writing. You will score poorly if a reviewer cannot readily find key information to compare yours with other proposals. As such, it is helpful to follow a formula that guides the reader from the big picture to the details. We have developed a set of 10 rules on how to best prepare your proposal. At Niche we have split these in what we call Success Factors (points that you need to present in the correct way) and Differentiators (factors that will make your submission stand out from the competition).

When writing your proposal it is advisable to stick to strict ethical guidelines. For funding proposals, this includes presenting information fairly and accurately (not 'overselling') and avoiding any form of plagiarism [2]. For example, it is best to avoid the controversial practice of re-using text directly from supporting manuscripts or past proposals.

Many funding applications fail, not because the funding body does not like the idea, but because the application is poorly prepared, documents requested are missing or your proposal simply does not meet the stated criteria. Proper research and preparation will reduce the possibility of this happening and ensure that the time you spend preparing your proposal is not wasted. Follow our ten simple rules and you wont go wrong. Alternatively, go straight to Appendix 1 to read about the seven deadly sins of funding applications.

Need Sells

Science tells us that giving makes us feel good [3]. Some of our greatest philosophers had commented on this phenomenon long before science proved it to be true.

"You have not lived today until you have done something for someone who can never repay you." — *John Bunyan*

"No one has ever become poor by giving."
— *Anne Frank*

"No one is useless in this world who lightens the burdens of another."
— *Charles Dickens*

When appealing for support it is your job to make the act of giving simple. Reward the 'giver' with the hope of value and removing fear of failure, over confidence and oversight on your part.

Rule #1: Target the right call (and follow their rules)

All funding calls have specific requirements that you must clearly show you meet [4]. Carefully read through any guidance and eligibility criteria published by the funding body. Generally, the number of hoops you have to jump through increases with the amount of funding you are asking for. You will be wasting your time if your application is not closely aligned with (and eligible for) a funding call.

Check the purpose and focus of the grant being offered, the size of funding available and the funder's grant-making philosophy.

- Does it fit with your needs?

- Can your project's requirements be tailored to the call's criteria?

- If a call requires partnering, consider whether you have a history of sharing responsibilities and resources with other organizations. Do you have a partner you could work with?

- Will you be required to find matching funds (where you must find additional money/ resources)?

Do your research before you even start thinking about writing. Speak to funders directly where that option is available.

- Look at past awards made by the funder and give careful consideration as to whether they mirror your project in scale, scope and focus.

- Does the funding body support organisations like yours?

- Determine whether the odds of receiving funding warrant the effort it will take to prepare a competitive proposal.

Hardman's Law of Frustration

Funding requests require applicants to provide substantial details on a diverse range of aspects around your proposal. The likelihood of funding correlates directly with the amount of time you dedicate to preparation. Everything takes longer than you think it will. For example, our FRAILOMIC application to the EU Horizon 2020 for €13 million ran to over 200 pages. Applications of this size take a considerable time to prepare and are likely to involve contributions from many authors/organisations.

$$N_0 = N\,e^{-dt}$$

$$N^{110\%} = N_0 - dx$$
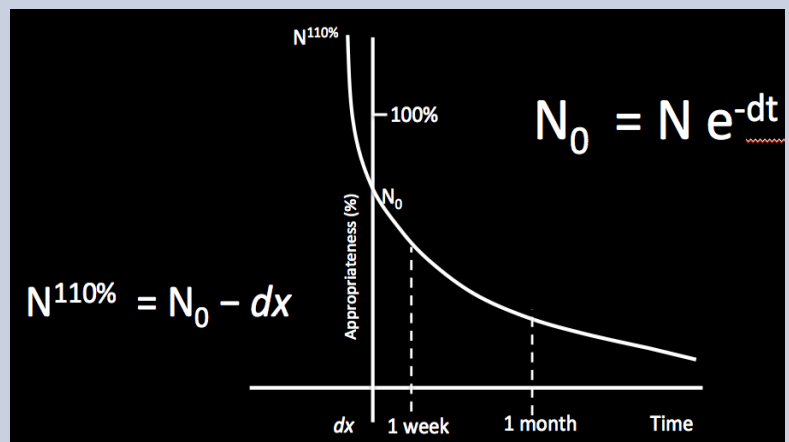
Hardman's Law of Frustration correlates the time you have to prepare your grant with its appropriateness for your project. Effectively, the call for submission becomes more appropriate the less time you have to prepare it. Suitability will increase to a point where it surpasses 100% a moment (dx) after the cut off date.

Rule #2: Have a great idea

NOTE: The proposal question, hypothesis or idea is considered the most important section of your submission [5,6].

An excellent way to be successful is to make the reviewer believe that what you are proposing is both new and exciting (and achievable). The best way to do this is to be able demonstrate it is empirically, providing relevant prior experimental/technical evidence and explaining clearly how previous results bridge to the proposed project. Be innovative – don't follow the herd:

- Be ambitious, but focused – select one or two single important challenges but don't overstretch the funders imagination.

- Be impactful – ensure your work will provide clear benefits – either to the scientific community or the public.

- Don't overestimate the 'pulling' power of new technology, on its own this will rarely get you funded.

State clearly what are you doing and why are you doing it. Present the knowledge gap that needs addressing and underline the uniqueness of your approach. A competitive implementation research application needs to:

- Pursue scientific questions that remain unanswered.

- Ask the type of questions where the answers advance knowledge (preferably with generalizability or applicability beyond a given setting).

- Provide a comprehensive background that can contextualise the problem and engage the interest of the reviewer.

Rule #3: Map out delivery

A great way to build confidence in potential funders is to have a clear and detailed plan of what you intend to do and how you intend to do it. In the words of Benjamin Franklin, "By failing to prepare you are preparing to fail."

Methods: Make the methodology you expect to use easy to understand. Start with a general project outline/design paragraph and use diagrams to illustrate the path to delivery. The text describing your methods will often be the most detailed and largest part of an application [5]. Take care, because it is the largest part of your application it is often the section with the greatest of number of errors (and potential to irritate your reviewer). Only include methods in the proposal, that you expect to use, are relevant to what you are measuring and how it relates to your objectives. Link the main areas of work together with their resource and management requirements. Assessors looking at your proposal will consider: Is the technical and methodological approach appropriate to the needs of the project and are the innovative steps achievable through the proposed approach?

Team: The people involved are just as important as the project you're proposing. Provide evidence that the team is
Governance   capable of delivering the work and detail the track record of the project participants. Do you have the right people for the job and how do you plan to manage the different collaborators, contributors, contractors and/or partners.

Demonstrate that you can feasibly conduct the work. Applications often utilise different team members who cover a range of disciplines, with different collaborators with different levels of experience making different contributions. A multidisciplinary project is often considered more creative than a project emanating from a single department as it integrates the analytical strengths of two or more often disparate disciplines to address challenges. Often this is where you find sparks of ingenuity.

Where possible, collaborate with experienced investigators who have conducted similar projects. When writing a collaborative proposal make it clear that you already have good working relationships with collaborators either via co-authored publications or co-presentations. In evaluating this, assessors will consider whether the project participants have the right mix of skills and experience to deliver the project successfully and whether the project has the potential to tap into the varied expertise base as necessary.

Rule #4: Define what success looks like

Part of convincing everyone that you know what you are doing is by showing clearly that you know where you are going. Define what you are trying to achieve and how you expect to demonstrate that you have achieved it.

Talk with your statistician early and often:

- What do you need to do to 'prove' your hypothesis?

- Will revising your approach to the question make the numbers less daunting?

- Will you need to revise your plans because of number problems (such as whether you will find enough cases to study) and if so how?

- What's the best analysis plan?

Rabbit Holes

'What if…' can kill your project. While curiosity is the mother of invention it can be a curse. When you start any new project your first steps often provide you with insights that can distract you as you dig deeper, possibly entering a 'hypothesis revision' loop that can lead you away from your primary objective. Convince funders of your unwavering conviction to your project goals.

Funding bodies recognise that projects are inherently risky, but seek assurance that those it funds have adequate arrangements for managing this risk. You should focus on the arrangements for managing and mitigating risk as follows: Identify the key risks and uncertainties of the project and provide a detailed risk analysis, including the technical, commercial, managerial and environmental risks as well as other uncertainties (e.g. ethical issues) associated with the project.

Identify key project management tools and mechanisms that will be implemented to give reviewers confidence that sufficient control will be in place to minimise operational risk and, therefore, promote successful project delivery. If you are creating a multidisciplinary project it should include a description of the arrangements made for managing consortium partner relationships and 'ownership' of the final output.

Rule #5: Provide clear budgets and delivery timelines

When seeking funding it is essential to establish just how much resource you need to complete your project [4]. Far too many projects stall when funds run out. Funding bodies have little appetite for supporting projects that do not have a clear budget and fail to demonstrate an understanding of when they will need to access them. Indicate the anticipated project cost making clear the level of contribution from any project participants.

- Assign different groups to each of the tasks and provide realistic budgets required to deliver them. Clearly outline how resources will be allocated (e.g., amount for salaries, travel, and equipment).

- Create a detailed budget justification (i.e., a description of why each type of expense is needed).

- Consider all forms of potential revenues (e.g., other grants and contracts, local funding, memberships, in-kind support), as well as all predictable expenses (e.g., staff salaries and benefits, consultants, travel, equipment, supplies, rent, insurance), for each year of the proposed project.

- Identify how you expect to source appropriate 'matched' funds or resources if applicable.

Fit expenditure to the project delivery timeframe. Fully break down the costs and justify them (for example provide quotations as evidence of expectations). Supporting information and explanation for project costs should also be provided wherever possible. It must be consistent with the category of work planned and development being undertaken within each work package.

If a project spans more than one type of funding (e.g., because significant work packages are in both fundamental and industrial research), you must describe and justify the breakdown of costs between each aspect. In evaluating this the assessors will consider the following questions:

- Is the budget realistic for the scale and complexity of the project?

- Does the financial support requested fit within the limits set by the specific competition?

- Is a financial commitment from other sources demonstrated for the balance of the project costs?

- Have any work package breakdowns been adequately described and justified?

- Does the project provide value for public money?

Include a narrative to justify the numbers. Pay attention to allowability, reasonability and allocability. It is almost certain that you will be required to justify your expenditure plans. Prepare to be interrogated. If your project is going to run for any length of time don't forget to include an allowance for cost increases and/or inflation.

Write with risk mitigation in mind

More and more funding bodies expect you to provide some form of assessment of the risks you are likely to face in attempting to deliver your project and how you expect to deal with each. Whether or not you are expected to provide a formal risk mitigation plan you should always work with risk in mind. Risks can be varied in nature such as:

Technical Risk: Ensure that your team has the technical competency to address challenges. Mitigation can include your team's broad skills set, breakdown of complex tasks into smaller challenges delegated to key individuals, establishing cross team communications channels and regular interactions.

Budgetary Challenges: Costs-based risk factors can be difficult to estimate. You can gain some security by seeking detailed estimates for proposed tasks from partners and suppliers. More detailed methods include Critical Path Method analysis. Don't forget to allow for cost inflation with longer projects.

Scheduling Risk: Defining how and when you expect to execute tasks will help to reduce risk. One approach is to ask the delivery team to provide a realistic assessment for each of the tasks allocated to them, building 'deliverables' into the project timetable or perform a shortest processing time assessment.

Rule #6: Write well and plan delivery

Take the time to create a high quality submission - the likelihood of funding generally correlates directly with the time you put into preparation of your application. The time it takes to write a proposal is hard to determine but we guess it ranges from 3 months to a year [5-8]. Write with the reviewer in mind. Treat your audience with care – guide them through your story. Do not make them work harder than they have to understanding your intentions:

- Write clearly.

- Use acronyms and abbreviations sparingly.

- Make sentences and paragraphs short.

- Avoid trite phrases and jargon.

Continue the same themes throughout:

- Regularly restate the specific aims and hypotheses verbatim in experimental design, methods and discussion sections [9].

- Outline how you will address specific aims and hypotheses in the analysis section aligning objectives, endpoints and deliverables.

Tell the reviewers how wonderful you/your team are - without telling them how wonderful you are:

- Convince reviewers that you are capable of doing the proposed work—they probably don't know you and so will have to rely on your judgement.

- Cite your relevant (collective) accomplishments factually and list relevant awards, publications.

- Recount prior work that is similar to that proposed.

- Avoid superlatives, self–aggrandizing phrases – let any letters of support provide them!

- Padding your proposal with irrelevant information will not impress the reviewers [9].

Using a writing style guide

Writing style guides can be helpful in facilitating the development of the funding application. Many well-recognised commercial guides are available. They ensure that all authors working on a project adopt a similar style and provide direction when contributors are unclear as to how to proceed. Guides can be a simple sheet of 'do's and don'ts' (often termed writing conventions) or complex documents providing instruction on English usage and project-specific phraseology. When used across a team preparing a large submission with multiple authors they serve to standardise the language of clinical source documents and expedite document delivery.

Quality and consistency are at the heart of Niche Science & Technology's philosophy, ensuring a reliable and dependable service. To this end, we have created writing guides to ease production, minimise proof corrections and enable schedules to be met. One benefit we have found is a reduction in the time required for document preparation. We have provided an example of a simple programme writing convention guide, often used by our teams (Appendix 2).
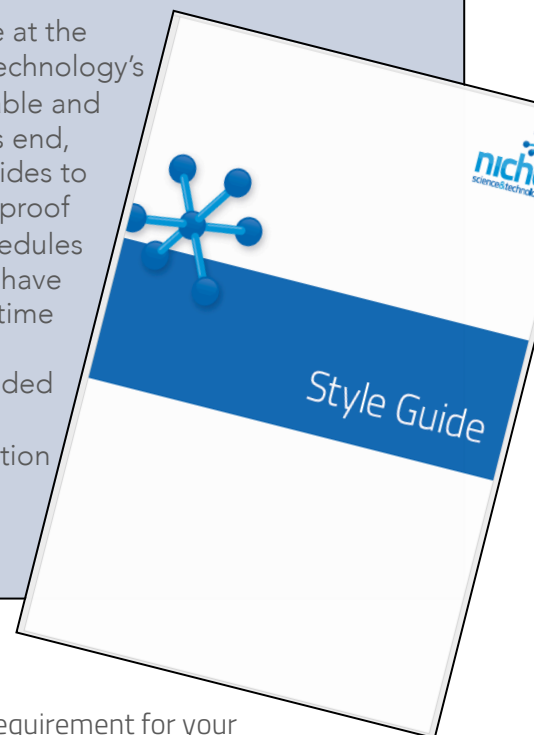
Rule #7: Describe your D&E plans

Telling the world about your scientific endeavours is more than a personal choice; it is a requirement for your success and often an ethical obligation. It is implicit that research involving humans and animals, for example, is only justified when the knowledge gained is shared. Reporting is doubly mandated when research is funded through donations and/or public funds. Funding bodies must demonstrate knowledgeable returns on their investments. In fact, many organisations have recognised the importance of information sharing. Requests for funding are now often required to provide details of how you intend to disseminate your findings and establish a lasting legacy for the work they support, implying that it is irresponsible to leave recognition of your findings to serendipity.

Good or bad, the number of people who see it (the size of your audience) influences the lasting impact of your work. Scientists have long recognised that they can reach a wider audience by targeting high impact journals. However, gaining access to top-flight journals can be challenging and a broader exposure isn't necessarily guaranteed. There is overwhelming competition in the current scientific literature for attention, with more than 2.5 million new titles being added each year. We are also bombarded with news articles, e-newsletters, blogs, podcast, videos etc. Even with the aid of powerful online search engines it is getting harder and harder for scientists to keep up to date and for authors to get their voices heard. More and more authors are coming to appreciate that there are other ways to increase engagement, and that a robust process of dissemination after publication builds stronger scientific reputations and increases opportunities for future support (have a look at our Insider's Insight on dissemination [10]). Your exploitation plan details how you expect to use your findings – whether that be to create a commercial product or to use your results to support funding requests for future work.

Rule #8: Define your legacy

More and more funding bodies are also demanding that their contributions have a lasting impact – a legacy [10,11]. This can be much harder to define than traditional objectives and endpoints. Will legacy be a change in clinical practice, treatment guidelines, continuation of the research or the formation of a self-funding organisation?

Create a business plan to anticipate what resources will be needed to sustain the organization or effort once the initial funding has been exhausted. This should include a description of the activities, services or products to be offered (i.e., who will do what, by when to implement chosen tactics for sustainability).

Create a future budget identifying the funds that will be needed to keep the project running and achieve its legacy goals, including:

- Projected expenses.

- Projected incomes - based on current sources of funding and other in-kind resources.

Use the anticipated budget to:

- Evaluate the financial resources needed to sustain the program.

- Identify ways to generate resources other than money (e.g., time, materials) to meet some of the anticipated expenses.

Indicate how you will use potential tactics to achieve financial sustainability, including:

- Sharing positions and resources.

- Becoming a line item in an existing budget of another organization.

- Incorporating the initiative's activities or services into another organization with a similar mission.

- Additional grants and/or investments.

Apparently, it's all good making discoveries, saving lives and inventing new medicines, Simon, but we are having hardly any impact on Twitter or Facebook

Rule #9: Put your best foot forward

As with any piece of work, you will be judged on the overall quality of your submission. Show how valuable and necessary your project will be. It only stands to reason that reviewers/assessors will equate a poor quality submission with high risk of project delivery. Don't gold-plate, pad or over-emphasize your stories. Speak the truth and stick to the facts.

Give yourself the best chance you can. Little things count! Presentation, punctuation and grammar set the tone for how people feel about your work – they really do matter. Some hints would be:

- Check spelling.

- Check calculations and due dates.

- Check the submission package, make sure all required forms, documents and necessary attachments are included, page number and font size requirements are followed and all components are provided in the order required.

Ask colleagues/proofreader to read/fact check the application:

- Are the goals clearly stated?

- Does the proposal clearly extend prior work in the field?

- Is the impact of your potential project completion obvious?

Don't forget to include the 10 key ingredients to assure reviewers of the significance, feasibility and impact of your proposition [12].

Rule #10: Plan for failure

A good idea is no guarantee of success and across many disciplines fewer than 20% of funding applications are accepted. Given the success rates the odds are clearly stacked against you. With this in mind, planning for rejection is a critical part of the application process [4]. As per Hardman's Law (page 3), timing is critical and it is advisable to line up a second and third credible option. As we have already discussed, government grants are a significant source of funding for researchers looking to get their idea off the ground and can represent a good investment of preparation time in terms of long-term academic recognition. However, finding grants that fit your work can be difficult and opportunities few and far between. Grant applications are often laborious and can be highly idiosyncratic to the agency at hand, making it difficult to re-direct a failed submission. Institutional or government grants are by no means the only source of non-dilutive funding out there and you should give consideration to other options. You might want to research into any interest you can generate in:

Patient advocacy groups: Also known as voluntary health agencies or non-profit disease foundations, patient advocacy groups are composed of mission-driven individuals seeking to combat a particular disease, disability, or group of disorders. They're often organized by a mix of laypeople and professionals, and they often work closely with doctors and large pharma. Many of them fund research on their particular area, like the American Diabetes Association, the Parkinson's Disease Foundation, the American Lung Association, or the Alzheimer's Association.

Foundations and family organisations: Foundations are set up by wealthy families to support specific causes or sets of causes. They often invest in areas they believe in or to which they have a personal connection. Social impact, often in the arena of human health, is a major focus of family foundations - the Bill and Melinda Gates Foundation is a good example. Because family offices are often a vehicle by which wealth can be passed down to the family's next generation, they may also offer investment in projects that have solid potential for commercialization.

Corporate foundations: Large life science corporations are increasingly pouring resources into corporate philanthropy organizations in order to improve consumer brand approval, communicate their key beliefs, inspire their stakeholders, and position themselves as constructive forces in their industry ecosystem. Major forces like pharmaceutical giants are also well-suited to understand the complex multi-year issues that life science projects face.

It's painful when your application isn't accepted but planning for this can help you be productive and successful. Once you have received notification of your rejection discuss the grant and any feedback regarding why it was rejected with colleagues, mentors and others. Get their advice and opinion on how to address any identified problems and how you can improve your plan. Identify an alternative funding source, consider their requirements and submit your new and improved application.

An interview with our Managing Director

Q What is the most challenging aspect of fund-raising?

A Having practical ideas comes second nature to most scientists and preparing submissions is relatively straightforward to anyone who has ever worked in research. The issue is generally the long lead times, low number of fitting opportunities and poor success rate. To address this any responsible organisation needs to see fund raising as an on-going process that never stops – always ready to move on to the next opportunity

Q How do you make yourself standout from other applications?

A Ultimately, any submission for funding that you put together needs to be a sales document. Yes, reviewers will want to ensure that your proposal is sound, that you have a plan that is rational and feasible and you are asking for a modest amount of funding. But that virtually describes every single application they will see. You need to appeal to their sense of value. If you are looking for a $1M donation, you want to present funders with a two million dollar vision! Developing a compelling case for support that outlines aspirational opportunities for giving is one of the most important steps you will take to support your fundraising

Q How do you give yourself the best chance when you seek funding?

A Part of the challenge when seeking funds is being on-target with your request – do you 'fit' in terms of the level of support they provide and the types of organisations/ projects they support? This is not always easy to determine from the standard information provided. Those looking for funding shouldn't fear reaching out to the granting/funding body to talk about their potential interest in a project. You might be able to determine whether they already have a project in mind for the funds they have available or an alternative source that fits better with your plans. Certain organisations expect there to have been some discussion with them before they even consider you for their shortlist.

And finally… Rule #11 for those running clinical projects

Since the concept of patient involvement in determining the course of healthcare and research was introduced nearly 25 years ago, the value of their contribution has rapidly been gaining recognition and acceptance. Until recently however, involvement has been seen as somewhat 'tokenistic', often limited to participation in trials or simply a biological source of samples, and therefore failing to fulfil its potential [13].

Despite little formal evaluation, patient involvement is believed to result in more meaningful outcome measures and may help to improve recruitment and retention in clinical trials. In the rare disease setting, inclusion of patient groups in fundamental and clinical research as equal partners has been reported to contribute to the success of research applications and the research conducted. In addition, funding bodies increasingly demand the involvement of patient organizations in grant applications and applicants' consortia. The Council for International Organizations of Medical Sciences recently revised their ethical guidelines for health-related research involving humans to address this topic.

It is worth noting that not all opportunities for patient involvement have the same impact and there is a risk of selecting only relatively simple activities, such as review of patient material or informed consent forms. While valuable, other aspects of involvement along the R&D pathway can have more strategic long-term impact but may be less straightforward and harder to implement. One good way to maximise return on your investment can be to involve patient representative bodies as we did with our RASP-UK initiative. Conducting studies in severe asthma, one of the differentiators recognised by the MRC was our partnering with Asthma-UK and their commitment to providing a 'Patient Input Platform' made up of well-informed patients (www.rasp-uk.org.uk).

Next steps

Effective fundraising – at the right moment, for the right reasons – is crucial to realising your vision. When attempting to achieve this it is always a good idea to have multiple irons in the fire. I hope you found this Insider's Guide useful. We created it to share with you a few pointers and helpful key learnings that we have developed over years of experience. Feel free to contact us if you would like to hear more about the role we played in winning over €150M in grants over a 5 year period from 2011.

Please contact me at the email address below if you would like further help and advice on writing your proposal.

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Appendix 1: Seven sins of funding applications

Proposal reviewers/assessors often have to work through a high number of applications. So, they are often grateful if you show one of these sins in your application because they can quickly kill your application.

SIN #1: WRITING FOR EXPERTS
Proposal review may be evaluated by a 'generalist' – someone not an expert in your field. Write accordingly.

SIN #2: NO HYPOTHESIS
You need to pose a hypothesis and yet proposals often aren't included. Make it easy to identify.

NEVER – write a hypothesis that includes expressions like
"The hypothesis is to study the role of our fantastic factor in XX disease" or "Our great factor modulates YY signalling". This is not a hypothesis.

A hypothesis that can be tested and falsified such as "Our factor decreases mortality in XX disease". Similarly, do not propose fancy techniques just for the sake of being highly modern.

SIN #3: SCREENING
Do not seek funding for a screening project, they are often seen as uninspiring.
Using fancy new technology might represent a exception to the rule but you need to give a full justification.

SIN #4: ANNOY THE REVIEWER WITH SLOPPINESS
One of the most annoying aspect of evaluating grant proposals are incomplete submissions or ones filled with errors.

SIN #5: ARROGANCE OR OVERAMBITION
Be modest and don't over-state your potential or ability.

SIN #6: OUT OF SCOPE
Do not waste your time and do not waste the time of the reviewers with off-topic proposals.

SIN #7: PROPOSE NEW AND CHALLENGING RESEARCH
The worst sin of all is to propose the new and exciting project you really want to start right now. The reviewers will hate it because you do not have preliminary data. If it is very challenging you may get low scores in feasibility.

Appendix 2: Writing convention – example

General
Always refer to product as 'The Lemonade'.

All clinical documents (e.g., clinical study reports [CSRs], clinical trial register summaries [CTRS], clinical CTD summaries, and Investigators Brochures [IB]) must be created in Microsoft Word using the correct Niche Science & Technology Ltd. template.

The Niche Science & Technology Ltd. of Style should be used as a resource for questions regarding writing style that are not addressed in this document.

The term 'subject' is to be used rather than 'patient'.

Style:
- The term 'adverse event' is used rather than 'adverse experience'.
- Capitalize all treatment groups;
- Upper case first letters will be used when referring to specific study days/visits, e.g., 'Day 1', 'Day 3–5' or 'Visit 1'; an en dash will be used between numbers of days, e.g., 3–5. When quoting extended visit windows hyphens may be replaced to avoid confusion e.g., Day -2 to Day 1.;
- Gender– caps (e.g., Male, Female);
- Race – capitalize (e.g., White, Black, Hispanic);
- Use UK spelling for reports used in the UK and US English spelling for reports prepared in the US. Words using US spelling within the template boiler plate text do not need to be changed to UK spelling for reports written within the UK and vice versa

Numbers
The European convention for dates is used (e.g., 01 January 2019 or 31-Jan-2019).
For whole numbers from one to nine, words rather than numerals are used, except when used in conjunction with units (e.g., 10 mg/L) or percentages (e.g., 10%) or when referring to a specific time point (e.g., 3 hours, Day 2).

For numbers greater than or equal to 10, numerals are used, except at the beginning of a sentence (e.g., Fifty subjects participated...).

A comma is not used for numbers greater than 1000 and less than 10,000 (e.g., 1500 not 1,500). A comma is used for numbers greater than 10,000.

Probability values are expressed as lower case 'p' without a space (e.g., p=0.001 or p<0.005).

Abbreviations
The following are examples of abbreviations that are suitable for use in the text and tables without being defined:
- Units - kg, mg, μg, mL and so on for all SI units, U for arbitrary units, IU for international units;
- Other standard abbreviations - IV, SC, PO, OD, MD, PRN, AM, PM, ITT, PP, bid, i.e., e.g., Mr, Dr, etc.

SUBMISSION WRITING CONVENTIONS FOR Niche's Sparkling Lemonade (cont.)

In addition, the following are suitable for use in in-text tables (but not the text without explanation)
- Year(s), month(s), week(s), day(s), hour(s), minute(s) and second(s) should be abbreviated to y, mo, w, d, h, min, sec, respectively
- Use M for male and F for female
- N=sample size; n=subset of sample size
- Standard deviation and confidence interval can be abbreviated to SD and CI, respectively

Other standard abbreviations to be used include:
- Adverse event: AE
- Serious adverse event: SAE

Appendix 2: Writing convention – example (continued)

<u>Spacing</u>

Do not use spaces when citing percentages e.g., 43%.
When citing ranges use a dash without spaces on either side (e.g., 55–65 ng), do not use the word 'to'.

<u>Hyphens, em and en dash</u>

Use a hyphen (dash without spaces on either side) in compound words that are used attributively to clarify the unification of the sense. For example:
- child-bearing; drug-related adverse event; Fifty-one subjects; on-therapy; placebo-controlled, double-blind, parallel-group study; Gram-negative; intent-to-treat; pre-dose, pre-therapy, post-dose, post-therapy.
- Hyphens should not be used for: per protocol; post menopausal; HIV positive
- The en dash (longer than the hyphen) is used to denote span in page ranges, unit values, and dates. It is also used as a link between two nouns.
- The em dash (longer than the en dash) is used in place of parentheses or to introduce an afterthought or a statement to summarize what has gone before.

Bullet Points/Numbered Lists
End a series of bullets with semi-colons, with the exception of the last bullet, which should be ended with a period. Example follows:
- one;
- two;
- three;
- four.