

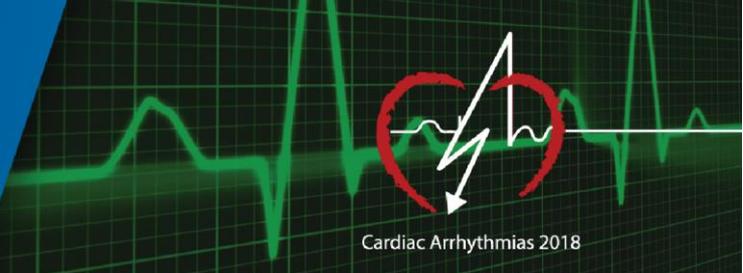
IDSS 2018

14th International Dead Sea Symposium (IDSS)

on Innovations in Cardiac Arrhythmias & Heart Failure

October 28-31, 2018 | Tel-Aviv

David Intercontinental Convention Center



Guidance Notes for applicants to the IDSS Innovation Awards 2018

Personal Information:

E-mail: Please ensure that you include a working email as this will be our primary method of contact. To prevent your mail from going missing we encourage you to use a mailing address that you know is reliable and will reach you.

If there are co-applicants, please add their details on the application. Only names of applicants inserted onto this form can be recognized on an Award if you go onto win.

Company Name:

Executive Summary (mandatory):

Please attach a formal executive summary, your business plan and financial projections.

Use this space to cut and paste a brief overview of your entry to allow the judges to get a quick summary of your company.

1. Category:

Which best describes the stage of advancement?

This is an important question to tell us the stage of **company formation**. State whether you are pre-incorporation or have incorporated and whether you are from a University as a spin-out. Also use this section to describe the stage of funding you are at from seed to a floated company.

Into what primary category is your innovation?

When describing your idea to someone, it is helpful to be able to categorize it into a box. For example, is it a service or a technology? The list below, gives broad categories of innovation that are useful to describe your innovation. Which of these areas does yours best fit into?

Certain entries might be applicable for more than one category; however, we only wish for you to pick the single category, which you feel best describes your innovation. For example a new electronic patient record should be classified as software based technology (although it could also be a service innovation).

- a) **Consumer Product:** this is an innovation that is designed to be sold directly to the patient / consumer such as a beauty product, a children's toy or a vitality product.
- b) **Diagnostic:** an innovation that is designed to detect a disease state or physiological measure. Diagnostic tests are broadly categorized into In-Vitro Diagnostics (including point-of-care) or Diagnostic Imaging tests. For our purposes, please choose this category if your innovation is any form of diagnostic tool or test.



Conference Secretariat:

15 Abba Even St. Herzliya 4676652, Israel Tel/Fax: +972-3-5767720

E-mail: idss@idss-ep.com Website: www.idss-ep.com

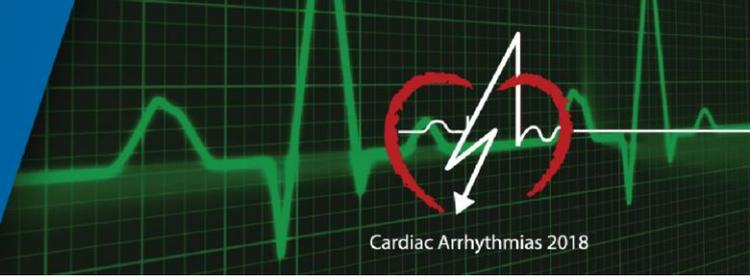
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- c) **Software based technology (sometimes known as ICT or Information and Communications Technology):** this category should be reserved for an innovation that is predominantly based on a novel application of soft or hardware or a combination of both. An example would be a computer program based on an algorithm that helps to aid diagnosis
- d) **Educational Tool:** an idea that aids clinicians, careers or patients to better understand, prevent, treat a condition. This category also includes training tools.
- e) **Medical Device:** a medical device is a piece of equipment used to diagnose, monitor or treat a condition or disease. The device would normally be subject to classification (I, II or III) and require CE marking to be sold in Europe and FDA approval to be sold in the USA. Entrants often get confused because a diagnostic can also be a medical device. This is very true and so we recommend you select the one you feel best describes your innovation, hence if it is predominantly used to diagnose disease, select diagnostic.
- f) **Service innovation:** Any innovation in the way a service is run, should be classified in this category. An example might be a more efficient way of running an out patients clinic or a novel mechanism to meeting targets.
- g) **Therapeutic:** this category should be reserved for innovations that employ novel drugs to treat disease.

2. What stage of development are you at?

- **Pilot/Prototype:** You have built a prototype or a bench-top model or for a service delivery you are running a pilot study.
- **Animal Studies:** Have you begun preclinical or animal studies? Have these been completed?
- **First In Man (FIM):** You have carried out a first in man study
- **Clinical Trials:** You are carrying out a clinical trial (post FIM)
- **Trading Business:** Your products are already on the market and are being sold.

3. Market, Marketing & Sales: what is your potential addressable market size (number procedures, ASP (average selling price) etc.)

The information need to base on market researches already done. If non official indications exist please estimate based on your experience.

4. Competitive advantage

What is Novel about your innovation? **(Max 60 words)**

To win an Innovation Award, your innovation needs to demonstrate an inventive step. A stepwise improvement in a product might not be considered novel, although the way you have gone about it might well be highly novel. Please try to emphasize what you consider to be novel about your entry explaining what steps you have taken to confirm its novelty. **THIS IS A CRUCIAL QUESTION FOR YOU TO ANSWER TO PERSUADE THE JUDGES TO GIVE YOU AN AWARD!**



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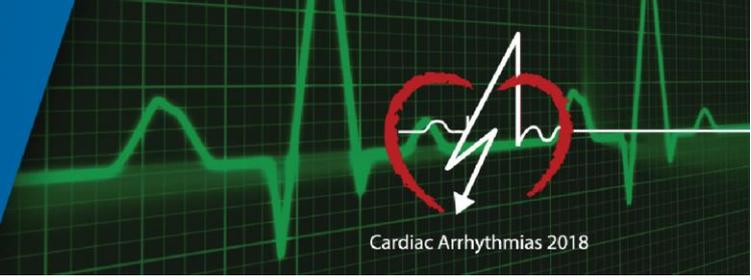
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5. Intellectual Property

Just like bricks and mortar, the output of your intellectual capacity can be bought, sold or licensed to a third party. Intellectual property (IP) encompasses patents, copyrights, trademarks, design rights and know-how and can be vital assets – helping you to secure funding for the successful development and adoption of your innovation. In certain circumstances, as Tim Berner's Lee did with the Internet, a decision is taken to publicly disclose one's IP to the general domain although one needs to understand the implications of this before one takes such a decision.

(5a) Have you applied for Patents?

On filing a patent you are issued with a patent filing reference number and a priority date (the date you filed). Please specify the reference numbers and the dates filed and/or granted.

(5b) Do you have any Trademarks?

If yes, please give details here, including reference numbers, dates filed etc.

(5c) Give details of any other form of Intellectual Property protection

There are other forms of IP, including Design Right, Know-How etc. State any other IP that you own and provide details (Max 60 words).

(5d) Please give details of who owns the intellectual property

Does the IP belong to a University, to your employer or is it yours? You may not have resolved this issue yet. If that is the case please state this here. If you have resolved it, state how.

If you have set up a Company what are the relative shares owned by each of the stakeholders? Has the IP been assigned to a Company? Are the rights to the IP licensed or sold? Give as much detail as possible; as often complex issues get identified in the Judging session and the more information you can give the easier it shall be to resolve in the Judging session. (Max 150 words).

6. Proof of Concept: This Is a Key Question – make sure you complete this section properly.

(6a) How have you obtained POC? (Max 100 words)

Proof of concept is a broad term that describes the steps you have taken, to develop the proof that your idea does what you say it does. It may help to think of POC in terms of clinical, technical and commercial validation, i.e. will it work? Can it be made? Will it be bought in sufficient numbers?

You are recommended to think about the following three areas when answering this question:

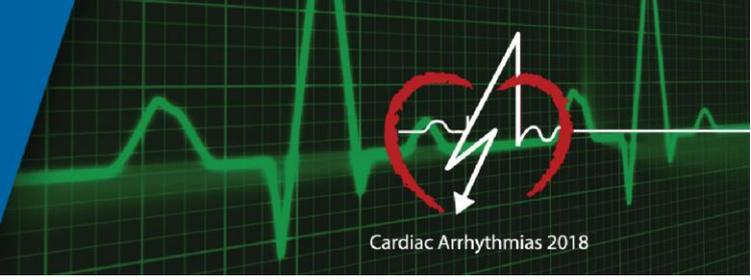
- I. **Clinical validation:** what evidence would you need to provide to clinicians to satisfy their concerns?
- II. **Technical validation:** what data would you need to obtain to manufacture the product and meet regulatory requirements?
- III. **Commercial validation:** Is the project viable? Is it cost-effective and is there a market for the product or service?

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***** If you have not taken any steps to validate your idea, you must state this *****

(6b) What further steps do you need to obtain proof of concept? (Max 60 words)

Although you might not have obtained sufficient proof of concept yet to meet the above three requirements, the Judges will be looking for evidence that you have thought through the steps you will need to go through and developed a road map. Please detail them in this answer.

(6c) Please give details of your regulatory strategy (Max 100 words)

Please give details as to whether you have CE mark in Europe or FDA approval in the USA. If you are planning to achieve these milestones please state this to be the case and whether you intend a 510k route in the USA or an IDE Trial.

7. Team / Business Information

In this section we would like you to demonstrate the team you have around you now.

(7a) List each of the team members and give a very brief outline of the skills they bring to the party.

(7b) Have you produced a business plan?

If you have an executive summary and/or business plan, please do send this to us in support of your application, as this can add a wealth of information that might not be reflected in the questions above. If you have a financial model or cash flow analyses then please also include this as this will add significant leverage to your application.

8. Funding / Commercial Arrangements

If you have received **funding**, whether from your own pocket, friends or families, **grant funding** (from a grant awarding body or a charity), a bank loan, or investment from angels or venture capitalists, it is important that you provide the Judges with details of this on your application.

Any commercial discussions or partnership with other organizations must be disclosed. If you have won previous Awards, state them here.

9. Next Steps

(9a) What is the primary reason for entering the IDSS Innovation Award?

For most entrants there will be multiple reasons that they are entering the Awards (i.e. all of the above!). That is fine, but this question is looking to ascertain your "prime reason" for entering only and so you can only select one answer. Be assured that there is no 'wrong' option and certainly this question is not a determinant of progression but will help the Judges identify how an Award can best help you achieve your goals.

10. Further Information

If you feel there is any additional information that will support your application, please state it here and attach to the email when sending your application form back.

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