PRIX GALIEN AWARDS

UNITED KINGDOM

ENTRY BROCHURE

2018

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PRIX GALIEN AWARDS

UNITED KINGDOM

"Prix Galien is a welcome initiative to stimulate creative research and promote excellence."

Barack Obama,
President of the United States of America

Respected, revered and globally renowned, Prix Galien recognition is the highest distinction that can be awarded to therapeutic innovation. Nobel Laureates have acclaimed it as a Nobel Prize for biomedical research. Political giants from Obama to Clinton and Blair to Ban Ki Moon have praised its prestige and purpose. And previous winners have transformed health outcomes for patients with life-threatening disease.

Independently validated by an esteemed panel of healthcare leaders and luminaries, Prix Galien judging maintains the highest standards of rigour and ethics.

If you're considering taking part, you'll be in the very best company.

Prix Galien was established in 1970 to recognise significant advances in biomedical research. It celebrates outstanding efforts to improve the human condition through the development of novel, high-value medicines and medical technologies. It is recognised in 17 countries across Europe and North America – with emerging markets in Asia and Latin America soon to follow suit.

The awards have evolved in line with the changing demands of healthcare stakeholders. Excellence is no longer defined by safety and efficacy alone. It is evidenced by the demonstration of innovation, patient outcomes and real-world value.

These core principles of value and innovation are at the heart of Prix Galien's UK franchise owner, ValueBase. Prix Galien provides a unique opportunity for life sciences companies to share their value messages and data with a panel of eminent healthcare leaders – and to reward excellence in biomedical innovation.

This brochure outlines how you can take part – and write your name in Prix Galien history.

"I thank the Prix Galien for recognising that a healthier world is a safer world and a more just world."

Ban Ki Moon
Secretary-General, United Nations

Award Categories and How to Enter

There are four Award categories for UK Prix Galien 2018:

- Innovative Product
- Medical Technology - *New for 2018*
- Orphan Product
- Real World Evidence

For the **Innovative Product** and **Orphan Product** Awards, the Judging Panel is looking for innovations that offer the most significant overall contribution to patient care in the UK in terms of clinical effectiveness, cost effectiveness and innovation. The relevance of the UK in any aspect of the submission needs to be emphasised.

The **Real World Evidence Award** recognises excellence in the generation, collection and application of observational data for a medicine to demonstrate health outcomes, real-world patient benefits or socio-economic gains. Entrants may include observational or health economic studies that have demonstrated high-value benefits in safety or efficacy, provided disease insight or shown evidence of the relative effectiveness of a medicine in real practice.

New for 2018, the **Medical Technology** Award recognises innovation in medical technology. The Judging Panel will focus on qualities such as implications of the development of the device for the future of biomedical science from bench to bedside, and innovation throughout the course of the device development, application, and/or clinical utility.

Entry and Judging Criteria

Applicants are requested to submit entries according to the guidelines and criteria provided.

AWARD CATEGORY	CRITERIA
Innovative Product	For products launched, granted a new indication or that achieved an Early Access to Medicines Scheme status in the UK during the period 1st January 2016 to 29th March 2018. Products granted marketing authorisation through EU centralised procedure, in the UK or available under the mutual recognition process, are admissible.
Medical Technology	For products that have received marketing approval in the UK by March 29th 2018, but not more than 5 years earlier, unless the award is for a new and innovative indication, which must have been added within the previous 5 years. Therapeutic and diagnostic products must be CE approved; provisional approvals are not sufficient.
Orphan Product	Products are eligible for entry if they have been granted Orphan Drug status in the European Union and/or the United States. Products launched, granted a new indication or that have achieved an Early Access to Medicines Scheme status in the UK during the period 1st January 2016 to 29th March 2018. Products granted marketing authorisation through EU centralised procedure, in the UK or available under the mutual recognition process, are admissible.
Real World Evidence	Open to all products that have received marketing approval in the UK by March 29th 2018, but not more than 5 years earlier, unless the award is for a new and innovative indication, which must have been added within the previous 5 years.

How to Enter

To enter, please first complete the **online Registration Form** at www.prixgalien.co.uk – and submit with a purchase order number to cover your entry fee before Wednesday 31st January 2018.

Entry Fees are listed within this Entry Brochure, as part of the guidelines for each relevant category.

The entry fee includes a specific number of places at the Awards Ceremony at the House of Commons, dependent upon the award category. There may an opportunity to purchase more seats after the shortlisting process.

All entrants agree to their Company/Brand being named in any UK Prix Galien publicity as a condition of entry.

All entrants agree to be filmed during the Awards Ceremony at the House of Commons, should their submission be shortlisted.

Wining entrants agree to be filmed at their company offices – for publication on the Prix Galien website – within one month of the Awards Ceremony.

Please find within this Entry Brochure guidelines on how to structure and format your entry submission.

Data Security and Confidentiality

The submission process is entirely confidential. Entries are stored on a secure server with access granted only to the Judging Panel and the UK Prix Galien secretariat.

All parties have signed non-disclosure agreements.

Submitting your entry

The following documents, in PDF format, should be sent to ValueBase by the **entry deadline** of **Thursday 29th March 2018:**

The Entry Form, signed by a Director or Business Unit Director of the company (this will be sent to you after you have registered)

The Submission Dossier

An additional copy of the **Executive Summary** from the submission

An optional **Supplementary Pack** of up to 10 peer-reviewed publications

These documents should be emailed to info@prixgalien.co.uk or uploaded on to a USB memory stick and posted by recorded delivery to:

UK Prix Galien Award
ValueBase Healthcare Ltd
PO Box 1538
High Wycombe
HP11 9JS

Important Dates for your diary

The closing date for **registration,** including receipt of a purchase order number, is **Wednesday 31st January 2018.**

The closing date for payment and receipt of **submissions** is **Thursday 29th March 2018.**

The **Awards Ceremony** will be at the House of Commons during the evening of **Wednesday 26th September 2018.**

Please see the FAQs for further information.

Formatting

To ensure submissions are comparable, Prix Galien has developed standard formatting and structure guidelines. Please contact us if you have any questions.

All submissions should be:

- A4, 1½ line spaced
- 12-point Arial font (this includes font size in tables)
- 2cm margin on all sides
- The use of footnotes is discouraged

The total number of pages per category (excluding reference list and any appendices) is as follows:

- Innovative Products Award – 20 pages
- Orphan Products Award – 15 pages
- Real World Evidence Award – 11 pages
- Medical Technology Award – 18 pages

The maximum number of pages to be included per section is itemised in the Guidelines below.

Supplementary pack of peer-reviewed papers (Optional)

There is no restriction on the number of articles that may be referred to within the submission. A supplementary pack of up to 10 peer-reviewed papers may also be included as an appendix. The judges will review these additional papers as supplementary evidence to evaluate your submission. These papers, supplied as PDFs, should best demonstrate the qualities of your product.

Guidelines - Innovative Products Award (20 pages)

Summary of Submission (1 Page)

This should orientate the reader to the context within which the product is used and the content of the application.

Concept (3 Pages)

This should include:

- Outline of how/why the product was developed
- Whether it involved a unique target
- Whether it involved novel screening techniques
- Complexity and originality of chemical/ biotechnological development

Clinical Evaluation (5 Pages)

This should outline:

- The phase 1, 2 and 3 clinical trials
- Use of novel approaches to dose-finding, trial design and analysis (e.g. Bayesian techniques)
- Results of phase 4 trials (where appropriate)

Economic Impact (5 Pages)

This should encompass:

- Cost effectiveness/utility analyses including a justification of the economic perspective adopted and the approach to the assessment of health gain
- Predicted budgetary impact on the UK healthcare sector
- Anticipated societal impact on the UK

Population Health Impact (5 Pages)

- Anticipated market size and penetration
- Comparisons with main competitors
- Anticipated patient impact
- The predicted population health gain

Conclusions (1 Page)

This section is not obligatory but applicants may wish to include conclusions about the merits of the product.

Entry Fee

£10,750 – includes 5 spaces at Awards Ceremony, if shortlisted.

Further Information

While the number of references used within your submission is unlimited, your submission may be accompanied by an optional pack of up to 10 peer-reviewed papers in support of your product. The judges will look at this pack as supplementary evidence to support your submission.

Guidelines - Medical Technology Award (up to 18 pages)

The Prix Galien judges look forward to welcoming a range of device submissions. This could include:

- Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination together with any accessories, including software used for diagnostic and/or therapeutic purposes.
- Submissions should be for products intended by the manufacturer to be used for human beings for the purpose of:
    - Diagnosis, prevention, monitoring, treatment or alleviation of disease
    - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
    - Investigation, replacement or modification of the anatomy or of a physiological process
    - Control of conception

Submissions should not include products which achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means, but they may be assisted in function by such means.

At this time the judging panel will not be considering entries pertaining to artificial intelligence.

Summary of Submission (1 page)

This should describe clearly the context and content of the submission and should include:

- The area of healthcare and indication for use of the device
- Outline of how/why the device was developed with a summary of data in support of the indication(s) to date and their relevance
- Emphasis on relevant detail regarding unique elements

Concept (up to 4 pages)

This section should outline the concept of the device and explain its originality. It should explain precisely how the device was developed and tested. Please present the rationale for the methodology of studies to explore proof of concept and/or efficacy/safety for use in humans.

Clinical Evaluation (up to 4 pages)

This should describe:

- Evidence underpinning the utility of the device, including clinical trial data where appropriate; include both efficacy and safety
- Data on health outcomes, real-world patient benefits or socioeconomic gains. Explain why particular outcomes were selected and comparators chosen
- Use of novel approaches to trial design and analysis
- Comparisons with any relevant competitors
- Details of current and planned studies, including collection of RWE, as the device is used in practice

Economic Impact (3 pages, if included)

This should encompass:

- Where available, cost effectiveness/utility analyses including a justification of the economic perspective adopted and approach to assessment of health gain
- Predicted budgetary impact on UK healthcare sector
- Anticipated societal impact on the UK

Population Health Impact (5 Pages)

This should consider:

- Market size and current/anticipated penetration
- Anticipated patient impact addressing unmet need
- The predicted population health gain

Conclusions (1 Page)

This section is not obligatory but applicants may wish to include conclusions about the merits of the product.

Entry Fee

£5,750 - includes 2 spaces at the Awards Ceremony, if shortlisted.

Further Information

While the number of references used within your submission is unlimited, your submission may be accompanied by an optional pack of up to 10 peer- reviewed papers in support of your product. The judges will look at this pack as supplementary evidence to support your submission.

Guidelines - Orphan Products Award (15 pages)

Products are eligible to enter this category if they have been granted Orphan Drug status in the European Union and/or the United States.

Summary of Submission (1 Page)

This should orientate the reader to the context within which the product is used and the content of the application.

Concept (3 Pages)

This should include:

- Outline of how/why the product was developed
- Whether it involved a unique target
- Whether it involved novel screening techniques
- Complexity and originality of chemical/ biotechnological development

Clinical Evaluation (5 Pages)

This should outline:

- The phase 1, 2 and 3 clinical trials
- Use of novel approaches to dose-finding, trial design and analysis (e.g. Bayesian techniques)
- Results of phase 4 trials (where appropriate)

Economic Impact (5 Pages)

This should encompass:

- Cost effectiveness/utility analyses including a justification of the economic perspective adopted and the approach to the assessment of health gain
- Predicted budgetary impact on the UK healthcare sector
- Anticipated societal impact on the UK

Conclusions (1 Page)

This section is not obligatory but applicants may wish to include conclusions about the merits of the product.

Entry Fee

£6,750 – includes 5 spaces at the Awards Ceremony, if shortlisted.

Further Information

While the number of references used within your submission is unlimited, your submission may be accompanied by an optional pack of up to 10 peer- reviewed papers in support of your product. The judges will look at this pack as supplementary evidence to support your submission.

Guidelines - Real World Evidence Award (11 pages)

Summary Of Submission (1 Page)

This should orientate the reader to the context and content of the submission.

This should include:

- Outline of how/why the research was developed with a summary of results and their relevance
- Emphasis on relevant detail regarding unique elements

Concept (3 Pages)

This should outline the concept and rationale behind the generation, collection and application of data to demonstrate health outcomes, real-world patient benefits or socio- economic gains.

This should include:

- Study design, outcomes and analysis
- A brief summary of any novel elements and how they were validated for inclusion
- A focus on novel elements of the research that went beyond licensing requirements (if applicable)

Economic Impact (3 Pages)

This should encompass:

- Cost effectiveness/utility analyses including a justification of the economic perspective adopted and the approach to the assessment of health gain
- Predicted budgetary impact on the UK healthcare sector
- Anticipated societal impact on the UK

Population Health Impact (3 Pages)

Relevant to the overall theme of your submission, this should consider:

- Anticipated clinical benefits
- Anticipated patient impact
- The predicted population health gain

Conclusions (1 Page)

This section is not obligatory but applicants may wish to include conclusions about the merits of the research.

Entry Fee

£10,750 includes 5 spaces at the Awards Ceremony, if shortlisted.

Further Information

While the number of references used within your submission is unlimited, your submission may be accompanied by an optional pack of up to 10 peer- reviewed papers in support of your product. The judges will look at this pack as supplementary evidence to support your submission.

Frequently Asked Questions

ValueBase

Who are ValueBase?

ValueBase is a responsive business intelligence company for the pharmaceutical industry. It provides personalised intelligence tools for professionals charged with demonstrating brand value.

We combine innovative digital technology with specialist healthcare knowledge to identify, aggregate and structure large, disparate open data sources – and turn disorganised data into meaningful analytics.

How is ValueBase linked to Prix Galien?

ValueBase is the new franchise-owner for UK Prix Galien. Its experienced team has a long-standing affiliation with the Awards, and its focus on value and innovation is aligned with the core principles of Prix Galien.

References

The guidelines state that references may be provided for no more than 10 peer reviewed journals. What does this mean?

Whilst there is no restriction on the number of articles referred to within your submission, peer-reviewed journal references are an opportunity for you to provide supplementary evidence to enhance the evaluation of your submission.

The submission may be accompanied by an optional pack of up to 10 peer reviewed papers in support of the product. The judges will look at this pack as supplementary evidence to support the entry.

Papers should best demonstrate the qualities of your product. They should be supplied as PDF documents. Any references provided will only be used for judging purposes.

Can any data on file and unpublished data/journals be included in the reference list or in the reference/ appendix pack?

No.

Can I refer to an appendix in the main body of the submission to save on the length of a section?

You may refer to an article/analysis in the appendix, but bear in mind the strongest arguments in support of your drug should be contained within the submission itself (the appendix will show evidence of your arguments).

A submission should be fully referenced with a list of references provided in an appendix. You do not need to provide copies of the articles you reference throughout your submission, unless these are part of your reference pack.

Because of the lack of recent published literature we are considering submitting posters which were presented at recent conferences. Will this be acceptable?

As long as they have been presented, posters are fine.

Do we need to submit marked up references?

The judges prefer to have clean references without mark-ups please.

Content

What is required for the anticipated patient impact section (as the predicted population health gain will include QALY data)? Does this include information on patient prognosis, general quality of life etc.?

You can include this sort of information if you have enough room. It will depend on how much population data you have. The subheadings are guidelines as to what you might like to include in this section.

There is a guideline of 20 pages in total. Are the sub-heading page lengths guidance rather than absolute and does each section need to start on a new page or can they run on one from the next?

The judges prefer you to stick to the guidelines, so 20 pages in total and the exact number of pages specified within each section. This therefore means that each section will start on a new page.

Due to the sensitivity of the data we are sharing would it be appropriate to have an NDA in place to respect the confidentiality of the content included within the submission?

We appreciate that some companies have concerns about the sensitivity of the data. ValueBase reassures entrants that all judges and ValueBase employees involved in the process have signed confidentiality agreements. Your submission will not be shared with anyone else.

Timelines

What are the timelines for registration and entry?

The closing date for registration is Wednesday 31st January 2018.

The closing date for payment and receipt of submissions/entries is Thursday 29th March 2018.

My product isn't due to get its license until Q1 of 2016 - I'm not sure if we will have the license by the registration/submission closing date, can I still enter?

Yes, do still register for the Awards. If your product does not receive its license in time you can re-register to enter the following UK Prix Galien Awards.

Shortlisting

Can we use the logo of the medal in our internal or external communications about being shortlisted?

Unfortunately not. Prix Galien regulations only allow winning products to use the medal on advertising and promotional materials.

Are you able to tell us who else has been shortlisted in our category?

We can provide this information once all shortlisted companies have been notified.

I want to write an internal piece for our website, I wondered if we are the only company who has submitted two nominations in different categories - could you let me know?

This information will be available once all companies have been notified about the shortlisting.

Award Ceremony

When is the Award Ceremony and what are the approximate timings for the event?

The Ceremony will be held at the House of Commons during the evening of Wednesday 26th September 2018.

The evening will begin with a drinks reception on the Terrace at 7pm, followed by dinner in the Members' Dining Room.

What is the dress code?

The dress code is black tie.

Prix Galien Winners

Can we use the logo of the medal in our internal or external communications about winning the award?

Yes, Prix Galien winners are informed about the regulations relating to the use of the medal when they receive their award.

If we win the Prix Galien in another country can we use this in our advertising materials in the UK?

You may use this information as long as you specify the country and abide by the rules for using the logo. Please contact the UK Prix Galien Secretariat for clarification of these rules if you are unclear.

International Prix Galien

Can you tell me more about the International Prix Galien please?

Winners of the Prix Galien in each country are eligible to enter the International Award. The UK winners in 2018 will be provided with information about how to enter.