



National Institute of Biomedical Innovation

Grant Frameworks : Japan

Second Session:

Orphan Designation Incentives and Grants around the World

Worldwide Orphan Medicinal Designation Workshop
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JAPAN

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Missions of NIBIO, JAPAN

- Create

By Challenging Innovation and the highest innovative drug development studies, We create knowledge and techniques.

- Connect

We'll be the bridges of wisdom between academies and industries, between Japan and all over the world.

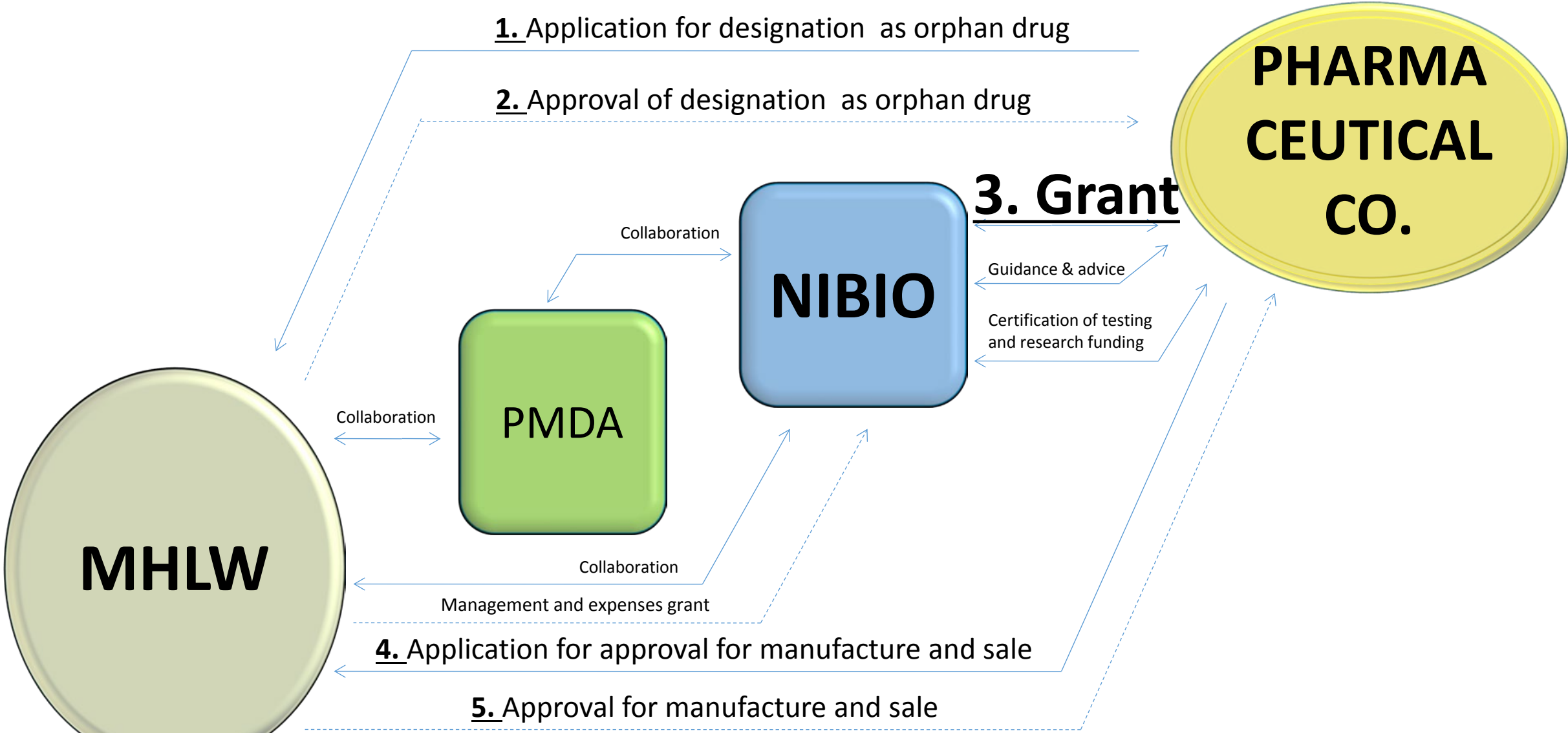
- Promote

We promote studies and developments for various patients and families with rare disease.

In-house study  Research funding for outside researcher



Process of the Orphan Designation Incentives in Japan



Grant Frameworks in Japan(1)

- We give the Grant after receiving the orphan drug designation from the Minister of MHLW.
- The maximum Grant amount is half of actual costs (including payroll costs).
- The period of Grant availability is three fiscal years.
- After obtaining approval of manufacturing and sales, the cooperation receiving the Grant funds may be asked to dominate to NIBIO.



Grant Frameworks in Japan(2)

Notes:

- For getting the Grant,
After receiving an orphan drug designation, you have to apply for the Grant to NIBIO.
- The Grant is NOT given to you automatically just for receiving an orphan drug designation.



Grant Frameworks in Japan(3)

Attention:

- For getting the Grant,
 - There must be the company, the office or the branch in JAPAN.
or
 - There must be the deputy of your company in JAPAN.
- Foreign companies can NOT apply the Japanese Grant outside Japan.

You have to set up the office in JAPAN or You have to designate the deputy of your company in JAPAN.



Development status of Orphan Drugs in Japan

Number of designated orphan drugs: 327

Number of the orphan drugs that received the Grant: 164

Number of the orphan drugs that get the approval of manufacturing and sales after receiving the Grant: 95

(1993-2013)

You can see the status of all designated orphan drugs in Japan for visiting this URL:

<http://www.nibio.go.jp/shinko/orphan/kisyoiyaku-hyo1.html>



Concluding remarks

For **getting the Grant** in Japan;

At first,

You have to receive **the orphan drug designation** from the Japanese Minister of MHLW.

Then,

You have to **apply** for getting the Grant **to NIBIO**, Japan.

At this time,

There must be your office or the deputy of you in Japan.

Finally,

You can **get** the Grant.

The maximum Grant amount is half of actual costs (including payroll costs).



Thank you

For more detail, please contact these URLs.

http://www.nibio.go.jp/shinko/orphan/pamphlet_english.pdf

(English)

<http://www.nibio.go.jp/shinko/orphan/pamphlet.pdf>

(Japanese)



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