



Comparator Sourcing Organisation

Comparators The “Check Nut” of Clinical Trials

By

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 What's A Check Nut ?

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 Comparator Sourcing Organisation - Roles and Services.

Check Nut !!


 Definition : A Secondary nut, screwing down upon the primary nut to secure it.

 A nut which is screwed up tightly against another nut on the same bolt or screw, in order to prevent accidental unscrewing of the first nut.




Check Nut !!

 Why comparators :

 Have you heard disclaimers such as : Manufactured by “**Non Patent Infringing Method**”

 So Until we Indians come up with : “**No need to prove comparison with Innovator - Method**” we will need comparators.

 Comparators help us stay on course and ensure we reach our goal.

 If we don't have an comparator then : **Jana Tha Japan, Pohooch Gaye Chin yane yane.....**


REVERSE PLANNING

- 🌐 What is Reverse planning ?
- 🌐 Conventional RnD approach do not work for Large Molecules / Bio-similars development
- 🌐 Top down approach of planning the development process, Trials, Study protocol etc... and then looking for Comparators is not workable in Today's scenario..... I am sure there are a number of victims of such planning sitting in this conference today. Where Comparator outage has disrupted the study.
- 🌐 Comparator supply is tightly controlled, supply chain restricted and Outages common
- 🌐 Comparators are the only element in your RnD process that is **not under your control**. It is a 3rd party product.
- 🌐 The **first thing** that's planned for, in an Army operations or **Risk Management** is for **elements** not in your control. **It's called Risk Reduction**
- 🌐 **So plan your comparator sourcing first and reduce your risks.**

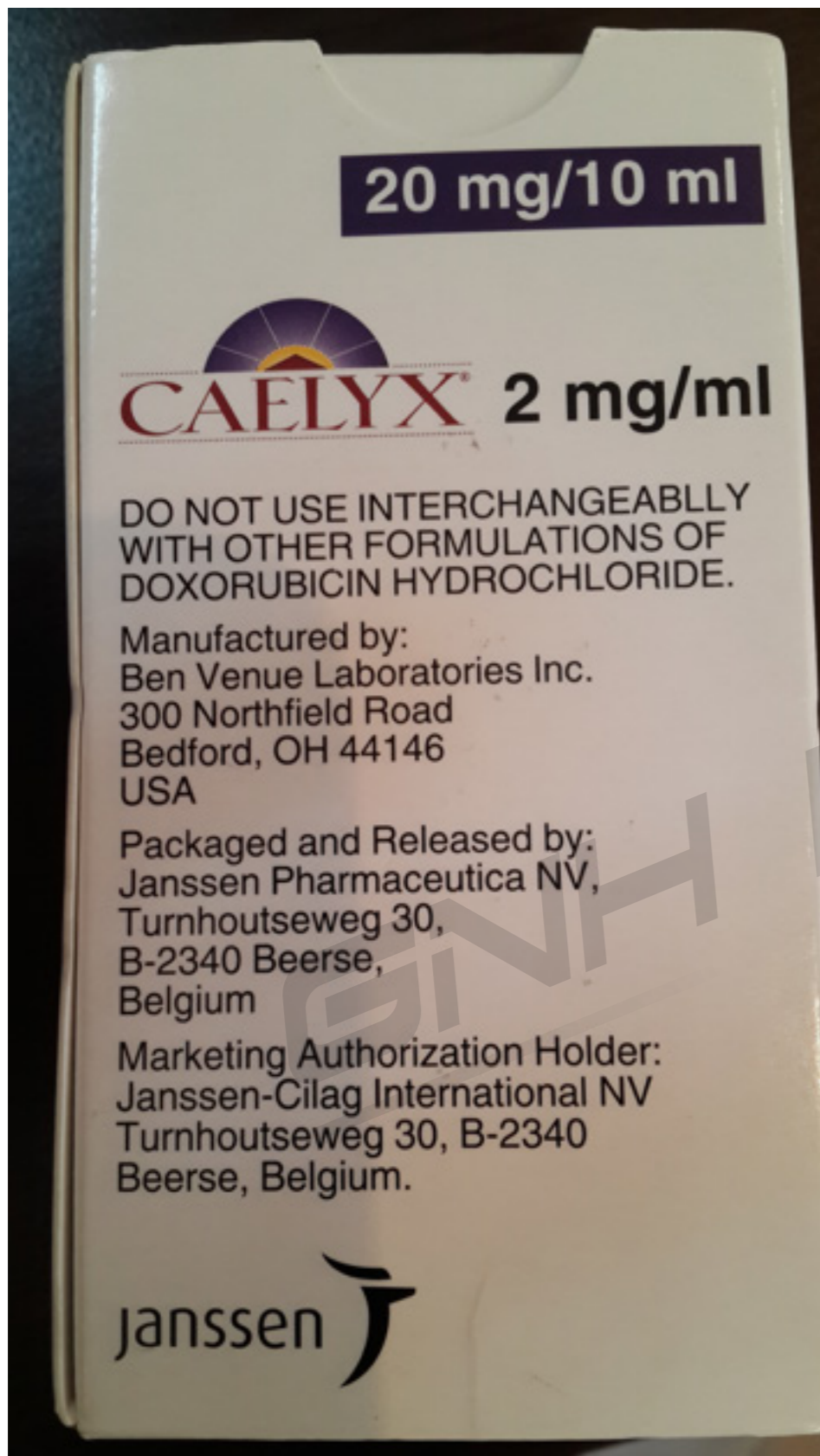
Source Market !

 What is your Destination Market ? Does any one ask this question ?

 For Example: a Bio-similar to be registered in EU needs a EU sourced comparator with **EU registration number** on the pack.

 While a Bio-similar for registration in **RoW markets** will accept comparator from any markets as long as it's from the innovator.

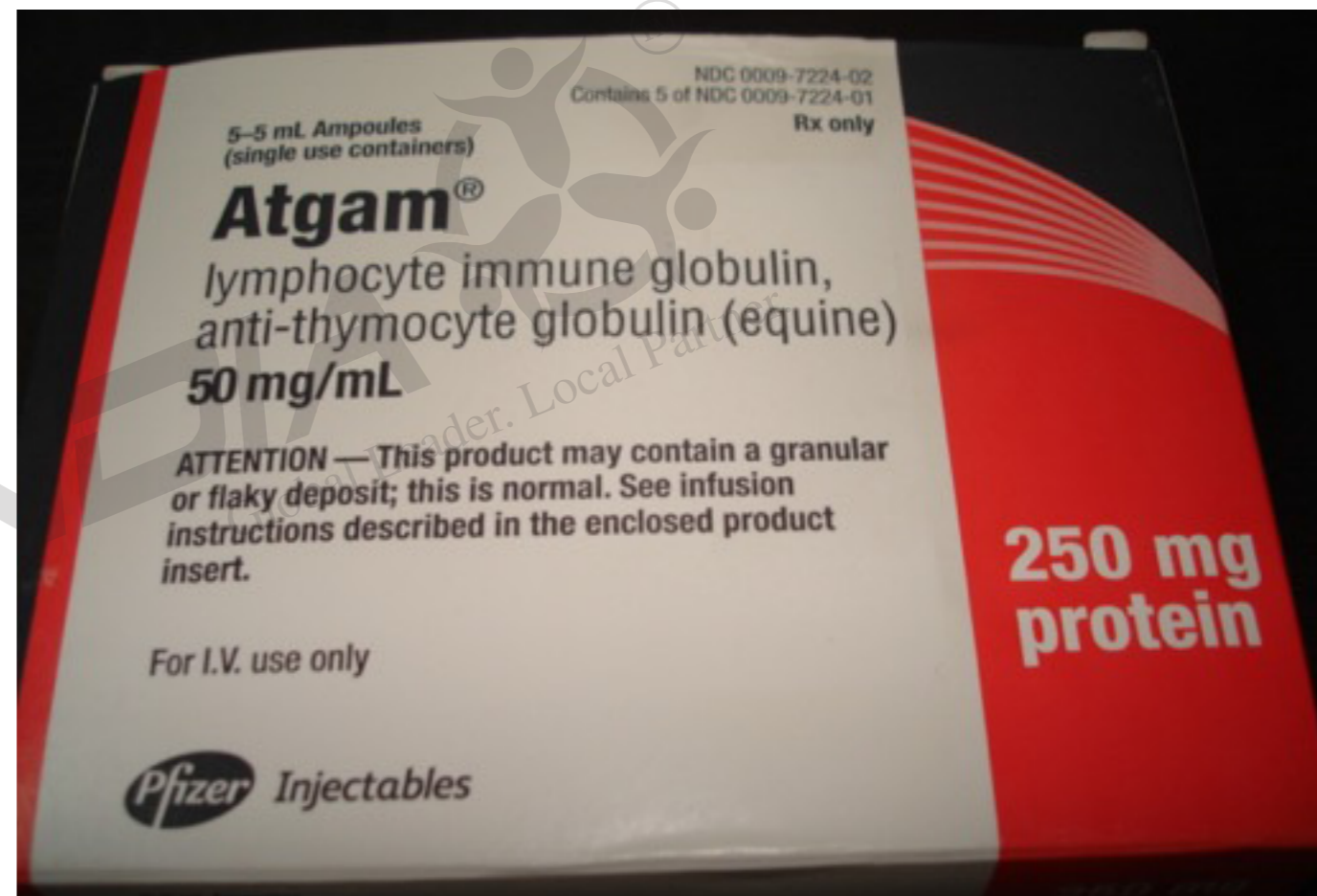
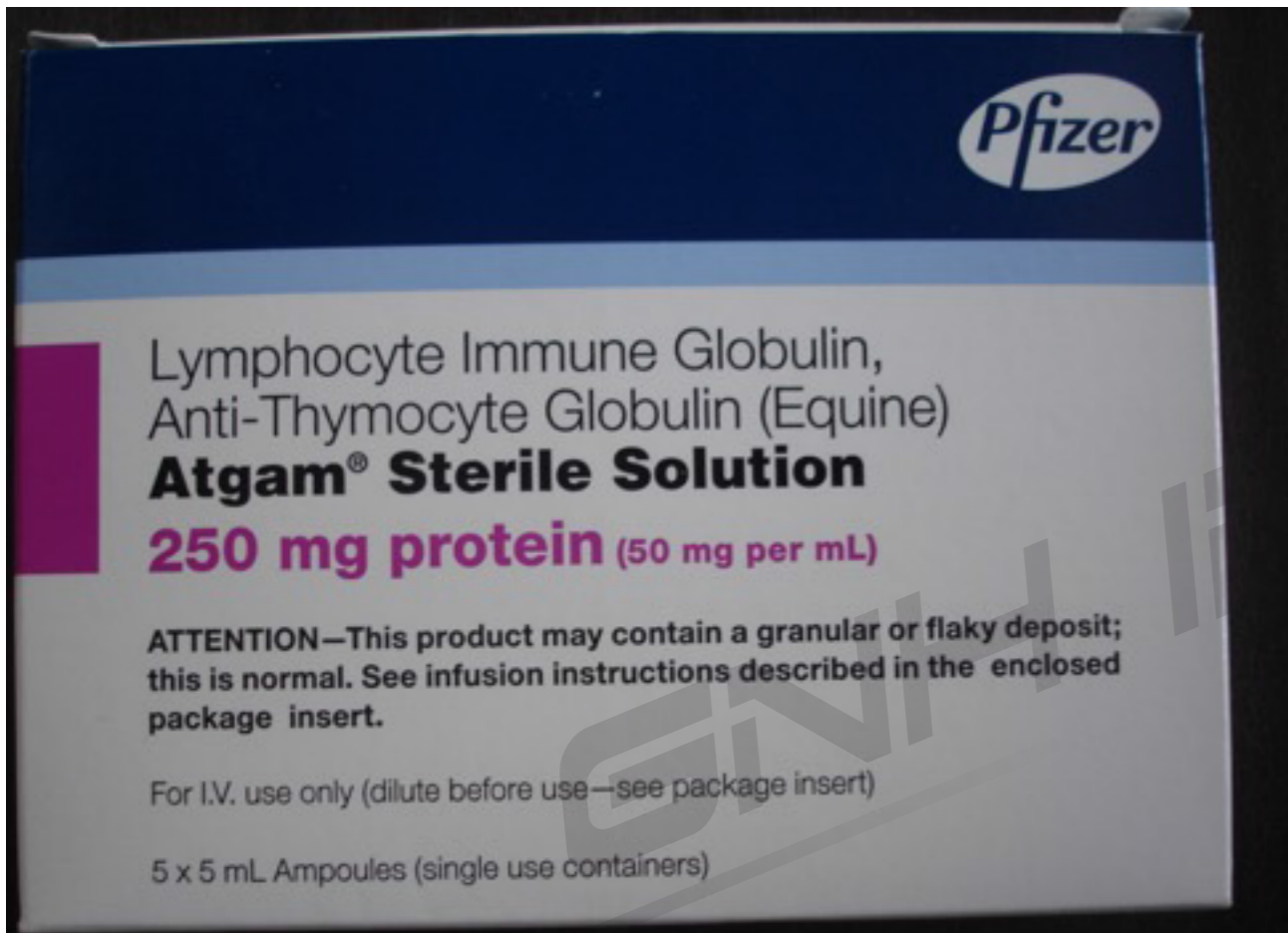
 The cost difference : 3x - 4x



Source Markets!

- 🌐 Source Markets should be chosen based on your Destination markets
- 🌐 For Example if you plan to Target RoW Markets, there's no point in sourcing products from US market
- 🌐 US products with NDC numbers are at least 3 time more expensive as compared to same brand in International packs
- 🌐 US stocks are difficult to get, highly controlled, traced and the sheer cost makes the development process un-viable.
- 🌐 In contrast to this : An International pack from Europe / Eastern Europe is available at 1/3rd the cost, in Large quantities, with multiple batches with Pedigree Documents.
- 🌐 It's easier to build Reference library with International packs than with US NDC stock.

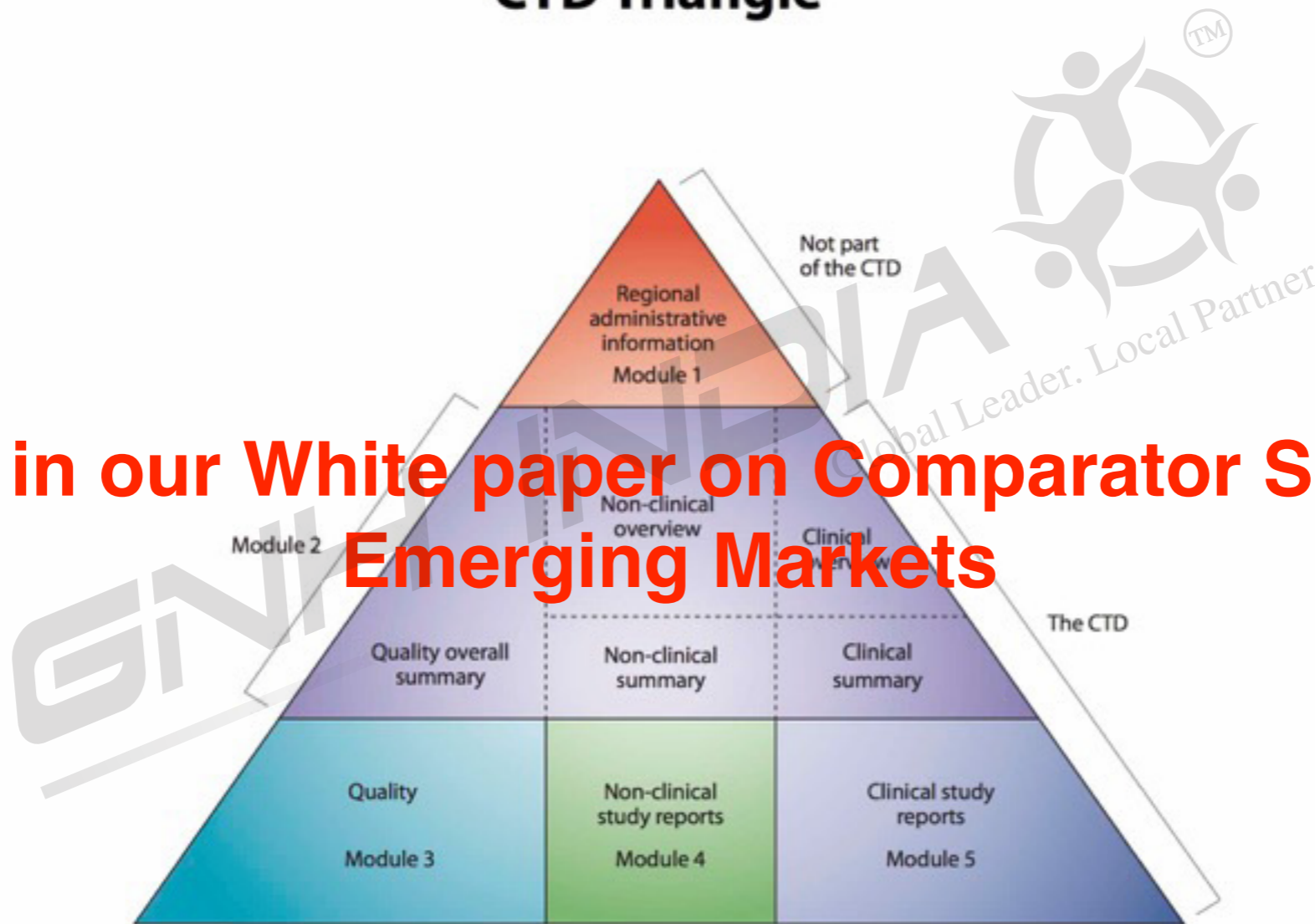
Market Intelligence



Source Markets!

Are they the same product ?

CTD Triangle




The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.




Read more in our **White paper on Comparator Sourcing from Emerging Markets**

Module 1 - CPP and FSC

Effects on Development process

-  Ultimate goal of any development is to **SELL** the product
-  **Sell - Fast and First to Market**
-  **Sell - At Most competitive price**
-  If your destination is RoW - there's no point in Sourcing of US / EU stock for development
-  Lack of reverse planning : Only increase development cost hence the END product COST
-  Lack of product availability from US / EU markets - delays development
-  And off course you are not FAST or FIRST to market

Key points in Sourcing Comparators

-  Identify your Destination Markets First
-  Check availability, Pack descriptions, SPC etc... of your comparator in planning stage
-  Call for Pack photos, Pack Scans in planning stage
-  Estimate the Quantity, Frequency etc.... in advance
-  Understand availability issues for Comparators right in the beginning.
-  Tie up your source even before you start development process
-  Ensure **Pedigree trail of your comparators**






CSO - Comparator Sourcing Organisation

- While Development and RnD is the a focus of Manufacturers or CROs
- Sourcing of Innovators / Comparators has become an “Achilles Heel” of this industry.
- An ideal CSO should be :
 - WHO cGSDP Certified Site
 - With validated Storage and Shipping systems
 - With Global Reach
 - Ability to source and transport products world wide
 - Knowledgable about Global Market place
 - In depth Experience in Sourcing, Imports and Exports process

GNH India - 1st CSO in India

-  A WHO GDP certified by SGS India
-  DFGT recognised Export house
-  Over 12 years of Industry Experience
-  Qualified QP on site in Warehouse
-  Fully licensed by State FDA and DGFT to carry imports and Exports of Drugs and related products
-  Over 135,000 products

GNH India - 1st CSO in India

-  Shipping and importing Globally to over 180 countries
-  Validated Storage and Shipping systems
-  Full Traceability and Pedigree for every supply
-  In Depth Market knowledge and Market intelligence
-  Complete Regulatory and compliance support up-till Market launch

Market Intelligence - 1 product - 2 packs ??

