



# *Where Are Berries on the Health Claims Research Pyramid ?*

Part 1 of 2



Spoon yourself some health!  
Eat colorful whole foods.

[follow the [Wikipedia](#) links]

Like Indiana Jones, every manufacturer of berry and superfruit products is after the [Holy Grail](#) -- a health claim approved by a regulatory agency like the [FDA](#).

In simple terms, a [health claim](#) would prove the berry or one or more of its phytochemicals has a direct effect on health either of a specific organ or general health of the person.

Another way of looking at it is the product would be deemed *required for health* so would get "[essential nutrient](#)" designation with a recommended [Dietary Reference Intake](#) value as vitamins and minerals have.

*Here's a point many miss:*

no berry or fruit pigment phytochemical has nutrient designation.

Not anthocyanins, not flavonoids, not ellagic acid,  
not \_\_\_\_ -- you fill in the blank.



*Take for example the rich content of  
anthocyanins and resveratrol in red grapes*

Red grape juice and grape resveratrol are well on their way through clinical trials to obtain health claim status, but have not yet been proved with sufficient science to say that specific effect is certain.

*How did they get to this lofty position in health research?*

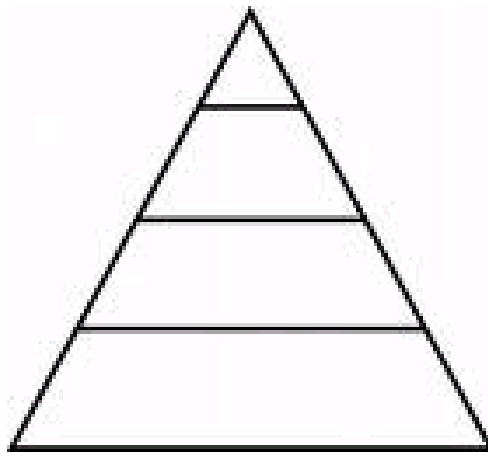
Grape juice, grape anthocyanins and grape resveratrol each has been called a dietary "antioxidant", but this term - although well-defined in test tube experiments - has not been proved for any dietary agent as effective with certainty in the human body except for vitamins A-C-E.

This was a topic of a recent essay in the Berry Doctor's Journal

[click here to read it](#)

## ***A Health Claims Research Pyramid***

Let's consider 4 steps *from bottom to top* through a pyramid.



Use the pyramid as a visual for the steps of science -- from bottom going up -- required to reach health claim status.

At the bottom is **step 1**, "in vitro" discovery. The **next step up, 2**, is for "in vivo" animal research. The **3rd step up** is for "first-in-human" studies. The **peak of the pyramid, step 4**, is where clinical trials are conducted.

1. At the bottom are experiments in the laboratory using in vitro ("in glass") experiments to define initial properties of an agent with unknown properties. Tests are done on isolated cells to define parameters like 1) range of doses causing the effect, 2) a mechanism of action, 3) specificity of effect, and 4) ability to inhibit the effect with a known blocking agent, further defining specificity.

2. Above in vitro experiments in the pyramid are tests in experimental animals to see the actions of the undefined compound in a living organism -- in vivo ("in life"). The same 4 procedures from the in vitro studies need to be replicated in vivo.

Steps 1 and 2 are wider because a) the focus needs to be open to possibilities (failure rate for experiments is high) and b) the potential time commitment is often very much longer in these discovery steps.

For even the most successful new agents -- whether from a plant or a new drug, steps 1 and 2 require a minimum of 10 years to complete !

Here's another truth: more than 90% of interesting phytochemicals (or synthesized new drugs) never get out of the bottom half of the research pyramid!

3. Ascending up the pyramid, Step 3 is the place for "first-in-human" studies where an exploratory dose and specific biomarker of organ response are examined. Safety is also an essential part of these studies, assuring there are no undesirable side-effects.

4. The peak of the pyramid -- Step 4, is where all the previous research gets focused to testing for a specific health claim in humans, usually those with a disease that the test agents supposedly relieves. This is called an "interventional" **clinical trial** ("intervenes" in the initiation or progress of a disease).

A complete Step 4 program is achieved through three stages of clinical trials in humans, Phase I through III clinical trials, which specifically determine whether a health benefit (or anti-disease action) occurs.

The fastest a tested compound can go through a complete Step 4 is about 8 years.

*Where are some berries and extracts we know within the research pyramid?*

Berry or Extract	Step Position in Pyramid	Forecast Year for Reaching Level 4 at the top	Forecast Year for Earliest Health Claim Approval
Acai	1	2014	> 2020
Anthocyanins	3	2010	2014
Blueberry	2	2012	2020
Cranberry	4	< 2008	2012
Red grape	4	< 2008	2012
Resveratrol	4	< 2008	2012
Goji	2	2014	> 2020
Red raspberry	1	2014	> 2020
Strawberry	2	2014	> 2020

- Forecasts are estimates based on current SSA
- Forecasts apply only if berry or its phytochemicals prove of positive benefit in successful clinical trials

*Next!*

- how research evidence is gathered to accumulate "significant scientific agreement" (SSA, an FDA term) making a berry or fruit phytochemical eligible for clinical trials
- why dietary **antioxidant polyphenols** we associate with benefit from eating berries and superfruits have not achieved SSA, are not approved with health claims, and are not deemed as valid "nutrients"

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