

Summary of Published Clinical Trials Demonstrating Efficacy from Microencapsulated DIM® (BR-DIM®)

The published clinical trials studying DIM have all used BR-DIM®

The BR-DIM® formulation was chosen for use in Clinical Trials after review and approval by FDA licensed Institutional Review Boards (IRBs). IRBs supervised all BR-DIM research performed by independent investigators. Pre-study IRB approval and supervision of clinical trials is required for subsequent peer-review and submission of study reports for publication.

SAFETY – TOLERABILITY - BIOAVAILABILITY				MICROENCAPSULATED DIM® - CLINICAL EFFICACY				
Published Clinical Trial (Trial Design)	Sex (“n”) = Number in BR-DIM grp	Safety and Tolerability Monitored	Bioavailability from DIM levels in Plasma/Urine	Promotion of Beneficial Estrogen Metabolism	Promotion of Higher SHBG	Breast Health	Endometrial Health	Prostate Health
Thompson et al. (PCDBT)*	F (47)	X		Increase in the 2OH/16OH Estrogen Metabolite Ratio P<0.001	Increase In SHBG P<0.001			
Zeligs et al. (PCDBT)*	F (36)	X		Increase in the 2OH/16OH Estrogen Metabolite Ratio P=0.05		Reduction in Average Breast Pain P= 0.03		
Kotsopoulos et al. (OLT)**	F (13)	X				Increase in BRCA1 in Carriers P=0.05		
Oettel et al. (OLT)**	F (8)	X					Reduction in Menstrual Pain and Bleeding P<0.05	
Dalessandri et al. (PCDBT)*	F (10)	X	Urine	Increase in the 2OH/16OH Estrogen Metabolite Ratio P= 0.059 ↑2OH P=0.02				
Ragoria et al. (OLT) **	F (7)	X	DIM in Plasma Urine, and Thyroid tissue	Increase in the 2OH/16OH Estrogen Metabolite Ratio P<0.05				

SAFETY – TOLERABILITY - BIOAVAILABILITY				MICROENCAPSULATED DIM® - CLINICAL EFFICACY				
Published Clinical Trial (Trial Design)	Sex (“n”) = Number in BR-DIM grp	Safety and Tolerability Monitored	Bioavailability from DIM levels in Plasma/Urine	Promotion of Beneficial Estrogen Metabolism	Promotion of Higher SHBG	Breast Health	Endometrial Health	Prostate Health
Hwang et al. (OLT) **	M (28)	X	DIM in Plasma DIM Levels Detected in Prostate in 93% of pts.					Lowering of PSA in 71% of pts and Nuclear Exclusion of AR In 96% of pts.
Heath et al. (OLT)**	M (12)	X	DIM in Plasma					Lowering of PSA
Gee et al. (PCDBT)*	M (30)	X	DIM in Plasma	Increase in the 2OH/16OH Estrogen Metabolite Ratio P=0.03				
Reed et al. (PCDBT)*	M,F (18)	X	Dose Responsive Increase in Plasma DIM					
Castañon et al. (PCDBT)*	F (373)	X	Urine					

*PCDBT = Placebo Controlled Double-Blind Trial **OLT = Open Label Trial SHBG = Sex Hormone Binding Globulin AR = Androgen Receptor

Clinical Impact of the BR-DIM Efficacy Endpoints: The importance of promoting and maintaining estrogen metabolism with greater 2-hydroxylation (2OHE_{1/2}) has now been established for all women, both **pre**-menopausal (Muti, et al.) and **post**-menopausal (Sampson, et al.). Benefits of higher 2OHE_{1/2} have also been demonstrated for Prostate Health in men (Barba, et al). The importance of higher SHBG levels as an indicator of Liver Health has been established in multiple studies (Jaruvongvanich et al.). Microencapsulated BR-DIM is the only formulation of DIM with efficacy demonstrated in Clinical Trials.

References:

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