

Clinically Superior Scalp Cooling

Superior results in the pivotal trial for FDA clearance

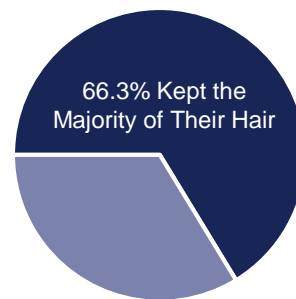
- The DigniCap Scalp Cooling System achieved **66.3% success** with taxanes in the U.S. clinical trial.
- The competitor's success rate was just 50.5% overall and 59% with taxanes in their U.S. clinical trial.

Longer clinical trial treatment evaluation period

More hair loss occurs with a greater number of treatments. For accurate evaluation, success must be measured at the end of treatment.

- In the clinical trial DigniCap was evaluated one month after the end of all the patient's chemotherapy cycles.
- The competitor's trial was evaluated after just four chemotherapy sessions.

CHEMOTHERAPY REGIMENS & DOSE	DigniCap N (%)	Controls N (%)
Totals	101	16
Docetaxel 75 mg/m ² & cyclophosphamide 600 mg/m ² every 3 weeks or 4-6 cycles	76 (75%)	10 (62.5%)
Paclitaxel 80 mg/m ² weekly for 12 cycles	12 (12%)	2 (12.5%)
Docetaxel 75 mg/m ² , carboplatin AUC 6 for 6 cycles every 3 weeks, trastuzumab weekly or every 3 weeks, with or without pertuzumab every 3 weeks	12 (12%)	3 (19%)
Docetaxel 75 mg/m ² , trastuzumab & pertuzumab every 3 weeks for 6 cycles	1 (1%)	0
Doxorubicin 60 mg/m ² & cyclophosphamide 600 mg/m ² every 3 weeks for 4 cycles	0	1 (6%)



Results when observed a month after the last chemotherapy cycle.

In comparison, 100% in the control group that did not use DigniCap lost more than half of their hair

View the complete description of the clinical trial at dignicap.com/research

Long-term Safety Follow-Up

As the first scalp cooling device to receive clearance in United States, Dignitana is the only provider to have data on long term safety.

TREATED SUBJECTS – SUMMARY OF ANNUAL FOLLOW-UP					
# in Primary Analysis 101	# Evaluable 91	# Annual Follow-up Assessments Completed			
		Year 1	Year 2	Year 3	Year 4
Evaluated		91	80	77	63
Disease Free		85	79	71	57
Recurrence					
Site of recurrence/ metastases		• Breast (2) • Liver	• Breast • Breast and bone	• Bone • Breast, bladder, GI, bone • Chest wall and supraclavicular lymph nodes	• Breast and nodes • Bone and liver • Breast, bladder, GI, bone • Thoracic and lumbar spine • Bone, liver, lungs, nodes
Scalp Metastases		0	0	0	0
New Cancers		0	0	Non-Primary Breast (1)	Thyroid (1)
Deaths		1	0	0	0
Lost to Follow-up		6	1	6	2



No scalp metastases have been reported 3+ years following completion of study treatment.