# International Breast Cancer Study Group
## IBCSG Biobank - Biological Material Availability - May 2019 for BIG 1-98, IBCSG 22-00, 23-01, 24-02 SOFT, 25-02 TEXT, 35-07 SOLE

For inquiries, please contact the IBCSG Translational Research Coordinator: Rosita.Kammler@ibcsg.org

| Trial Information | | | | | FFPE Blocks/cores / Blood samples | | | Translational Research: Completed, ongoing or to start (listed here to not replicate) | Publications | Overview Data Genomic and Transcriptomic Data | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Trial | Main endpoints | URL (public) | URL (members) | Follow-up | Type | Patient count | Available | % | Trial | | | | |
| **IBCSG 18-98 / BIG 1-98**<br>**Adjuvant therapy for postmenopausal patients with operable breast cancer who have estrogen receptor or progesteron receptor positive tumor**<br>Tamoxifen vs. letrozole vs. tamoxifen followed by letrozole vs. letrozole followed by tamoxifen | Disease-free survival (DFS)<br>Overall survival (OS)<br>Systemic disease-free survival (SDFS) | http | http | 8 years median follow-up (> 10 years) | **Primary tumor** | 8028 | 4671 | 58% | IBCSG 18-98 / BIG 1-98 | TR 4 BIG 1-98 SNP Leyland - Jones **CYP2D6, CYP19A1, ESR1-2**<br><br>TR 1 **Molecular profiling**, Swiss cohort, RNA, Aebi, Jaeggi<br><br>TR 15 a **GGI So**itriou<br><br>TR 5 BIG 1-98 **DASL**, Leyland-Jones ongoing + **TILs**<br><br>TR 7 Sninsky Prognostic Expression Signature<br><br>TR 24 Hazra, Regan MM, **Androgen Receptor signaling** as a predictor of outcome in ER+ breast cancer / BIG 1-98 TMAs<br><br>TR 31 Oesterreich, Association between loss of functional **E-cadherin** and response to endocrine therapy BIG 1-98 TMAs<br><br>**TR 33 BIG 1-98** IBCSG-Novartis; **Genomic alterations**. **Deep sequencing** at Foundation Medecine on 500 cases. Archival DNA. Presented at SABCS 2016. Manuscript submitted. | TR 4 -<br>Regan MM, Leyland-Jones B, et al. CYP2D6. J Nat Cancer Inst 104:441-451, 2012.<br>Leyland-Jones B et al. CYP19A1. Breast Cancer Res Treat 151:373-84, 2015.<br>Leyland-Jones B et al. ESR1 and ESR2. Breast Cancer Res Treat 154:543-555, 2015.<br><br>TR 1 - Antonov et al. BMC Cancer 10:37, 2010.<br><br>TR 15 a - Ignatiadis et al. JAMA Oncol. 2015 Dec 3. | **CYP2D6** (published, data available)<br>**CYP19A1** (published, data available)<br>**ESR1 and ESR2**. (published, data available)<br>**Androgen Receptor** (ongoing 2018)<br>**E-cadherin** (ongoing 2018)<br>Genomic alterations. **Deep sequencing** at Foundation Medecine (data in, pending full publication)<br>**RNAseq** (planned by IBCSG)<br>**DNAseq** (planned by IBCSG) | |
| | | | | | **ExtractedDNA** | | 3600 | 45% | | | | | |
| | | | | | **Extracted RNA** | | 2000 | 25% | | | | | |
| 50 patients per TMA with 2x 1mm cores/patient | | | | | **77 TMA's IBCSG cohort** | | 3798 | 47% | 50 patients per TMA with 2x 1mm cores/patient | | | | BIG 1-98 |
| 18 patients per TMA with 2x 2mm cores/patient | | | | | **72 TMA's Danish cohort** | | 1296 | 16% | TMA with 2x 2mm | | | | |
| **IBCSG 22-00**<br>**Low-dose cytotoxics as "anti-angiogenesis treatment" following adjuvant induction chemotherapy for patients with ER-negative and PgR-negative breast cancer** | Disease-free survival (DFS)<br>Overall survival (OS)<br>Systemic disease-free survival (SDFS) | http | http | 6.9 years median follow-up (in 2015) | **Primary tumor** | 1086 | 1028 | 95% | IBCSG 22-00 | **TR 25 Colleoni et al.** Prognostic and Predictive factors in endocrine unresponsive breast cancer patients.<br><br>**TR 27 Curigliano, Pruneri:** CD3 and CD20 lymphocytes infiltration and immune-modulation of regulatory T cells of adjuvant cyclophosphamide in TNBC<br><br>**TR 44 Sotiriou et al, Bordet:** Characterization of triple-negative breast cancer (TNBC) molecular subtypes based on Lehmann classification by gene-expression profiling, copy number aberrations (CNAs) and targeted sequencing | 332. Pruneri et al. Tumor-infiltrating lymphocytes (TILs) are a powerful prognostic marker in patients with triple-negative breast cancer enrolled in the IBCSG phase III randomized clinical trial 22-00. Breast Cancer Res Treat 158:323-331, 2016. (IBCSG 22-00) (Journal impact factor 4.08 | Tumor-infiltrating lymphocytes (**TILs**) (published, data available)<br>**PD-L1 / PD-1 / CD68 / CD8 / KERATINS / DAPI** (ongoing)<br>**CD3 / CD4 / FOXP3 / CD8 / KERATINS / DAPI** | IBCSG 22-00 |
| | | | | | **Normal tissue** | | 970 | 89% | | | | | |
| **IBCSG 23-01**<br>**A randomized trial of axillary dissection vs. no axillary dissection for patients with clinically node negative breast cancer and micrometastases in the sentinel node** | Disease-free survival (DFS)<br>Overall survival (OS)<br>Systemic disease-free survival (SDFS) | http | http | 10 years median follow-up | **Primary tumor** | 934 | 870 | 93% | IBCSG 23-01 | | | | IBCSG 23-01 |
| | | | | | **Normal tissue** | | 814 | 87% | | | | | |
| **IBCSG 24-02 (SOFT) / BIG 2-02**<br>**A phase III trial evaluating the role of ovarian function suppression and the role of exemestane as adjuvant therapies for premenopausal women with endocrine responsive breast cancer**<br>Suppression of Ovarian Function Trial (SOFT) | Disease-free survival (DFS)<br>Overall survival (OS)<br>Breast cancer-free interval (BCFI)<br>Distant recurrence-free interval (DRFI) | http | http | 8.0 years median follow-up | **Primary tumor** | 3066 | 2335 | 76% | IBCSG 24-02 (SOFT) / BIG 2-02 | **TR 32 Loi:** The landscape of cancer genes and relation to prognosis in premenopausal newly-diagnosed, hormone receptor positive breast cancer using tumor samples from the SOFT trial (Suppression of Ovarian Function Trial)<br><br>**TR 50 Goetz, Mayo Clininc:** CYP2D6 genotyping in the context of the IBCSG 24-02 clinical trial.<br><br>**TR 48 see** below combined SOFT and TEXT. | 316. Regan et al. Predictive value and clinical utility of centrally assessed ER, PgR, and Ki-67 to select adjuvant endocrine therapy for premenopausal women with hormone receptor-positive, HER2-negative early breast cancer: TEXT and SOFT trials. Breast Cancer Res Treat 154:275-286, 2015. (IBCSG 24-02 and 25-02)<br><br>326. Bellet et al. Twelve-month estrogen levels in premenopausal women with hormone-receptor positive breast cancer receiving adjuvant triptorelin plus exemestane or tamoxifen in the SOFT trial: the SOFT-EST substudy. J Clin Oncol 34:1584-1593, 2016. (IBCSG 24-02) | **ER, PgR, and Ki-67** (published)<br>**Estogen levels** in sub set of SOLE EST (published)<br>**Sequencing** full cohort- Loi (ongoing 2018)<br>**CYP2D6** genotyping (ongoing 2018)<br>**Breast Cancer Index** (planned)<br>**RNAseq** (planned by IBCSG)<br>**DNAseq** (planned by IBCSG) | IBCSG 24-02 (SOFT) / BIG 2-02 |
| | | | | | **Normal tissue** | | 1780 | 58% | | | | | |
| | | | | | **TMA tumor** | | 272 | 9% | | | | | |
| N.A. Pharmacogenetic , consent limitations | | | | | **Whole Blood, NA pts only, at Mayo** | | 659 | 21% | Pharmacogenetic consent | | | | |
| SOFT EST | | | | | **Serum** | | 120 | 4% | SOFT EST | | | | |
| **IBCSG 25-02 (TEXT) / BIG 3-02**<br>**A phase III trial evaluating the role of exemestane plus GnRH analogue as adjuvant therapy for premenopausal women with endocrine responsive breast cancer**<br>Tamoxifen and Exemestane Trial (TEXT) | Disease-free survival (DFS)<br>Overall survival (OS)<br>Breast cancer-free interval (BCFI)<br>Distant recurrence-free interval (DRFI) | http | http | 9.0 years median follow-up | **Primary tumor** | 2672 | 2187 | 82% | IBCSG 25-02 (TEXT) / BIG 3-02 | **TR 48 Schnabel, Biotheranostics Inc. IBCSG 24-02 and 25-02, R. O'Regan, Uni of Wisconsin:** Breast Cancer Index and prediction of treatment benefit of ovarian function suppression plus adjuvant exemestane versus tamoxifen alone in endocrine responsive, early stage breast cancer. | see 316. above.<br>337. Johansson et al. Impact of CYP19A1 and ESR1 variants on early-onset side effects during combined endocrine therapy in the TEXT trial. Breast Cancer Res 18:110, 2016. (IBCSG 25-02) | **CYP19A1 and ESR1** variants (published, data in)<br>**Breast Cancer Index** (planned)<br>**RNAseq** (planned by IBCSG)<br>**DNAseq** (planned by IBCSG) | IBCSG 25-02 (TEXT) / BIG 3-02 |
| | | | | | **Normal tissue** | | 2031 | 76% | | | | | |
| | | | | | **TMA tumor** | | 268 | 10% | | | | | |
| TEXT TR | | | | | **Pts w/both Blood & Block (Feb 2014)** | | 1582 | 59% | | | | | |
| | | | | | **Whole Blood (DNAextracted)** | | 1983 | 74% | TEXT TR | | | | |
| Bone Substudy 5 timepoints = 57pts complete Oct 2016 | | | | | **Serum** | | 119 | 4% | Bone Substudy 5 timepoints = 57pts complete Oct 2016 | | | | |
| **IBCSG 35-07 (SOLE) / BIG 1-07**<br>**A phase III trial evaluating the role of continuous letrozole versus intermittent letrozole following 4 to 6 years of prior adjuvant endocrine therapy for postmenopausal women with hormone-receptor positive, node-positive early stage breast cancer**<br>Study Of Letrozole Extension (SOLE) | Disease-free survival (DFS)<br>Overall survival (OS)<br>Distant disease-free survival (DDFS)<br>Breast cancer-free interval (BCFI) | http | http | 5.0 years median follow-up | **Primary tumor** | 4884 | 4113 | 84% | IBCSG 35-07 (SOLE) / BIG 1-07 | **TR 39 Colleoni, Barberis et al.** Targeting late recurrence after adjuvant treatment for early breast cancer (Trial: IBCSG 35-07 SOLE) | | **SNV** for 403 / **CNG** for 499 (to be presented in 2018, data available 2019)<br>**RNAseq** (planned by IBCSG)<br>**DNAseq** (planned by IBCSG) | IBCSG 35-07 (SOLE) / BIG 1-07 |
| | | | | | **DBCG TMAs primary tumor and normal tissue** | | 440 | 9% | | | | | |
| | | | | | **Normal tissue** | | 3165 | 65% | | | | | |
| SOLE EST at SOLTI (B,9,10.5,12) | | | | | **Serum/ Whole Blood** | | 89 | 2% | SOLE EST at SOLTI (B,9,10.5,12) | | | | |

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