

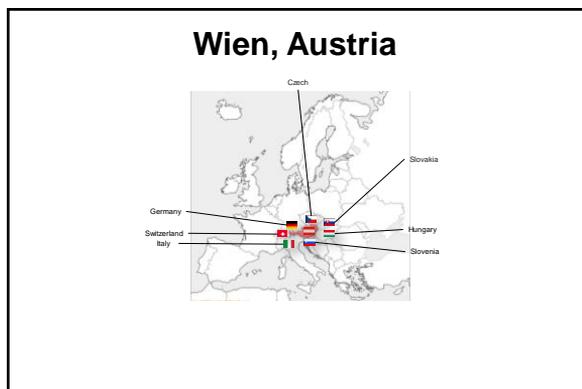


回	開催年	主なポイント
1	1978	ヨーロッパ各国の術後治療に関する意見統一をはかる
2	1984	n(+)症例では術後薬物療法が必要
3	1988	n(-)症例でも術後薬物療法が必要な場合がある
4	1992	n(-)症例を「low risk」「high risk」に分類 (リスクカテゴリー)
5	1995	n(-)症例を「minimal risk」「low risk」「high risk」に分類
6	1998	n(-)症例を「low risk」「intermediate risk」「high risk」に分類
7	2001	n(-) と n(+)がひとつの表に統合
8	2003	予後因子と予測因子を区別する考え方を導入
9	2005	脈管浸潤を予後因子として追加 (この年のASCOで術後trastuzumab)
10	2007	リスクよりもターゲット(ホルモン受容体、HER2)重視
11	2009	リスクカテゴリーからリスクレシヨルドの考え方へ
12	2011	サブタイプ別治療戦略 乳がんの生物学的多様性への対応
13	2013	前回の理念を踏襲しさらにブラッシュアップ
14	2015	足踏み状態 風の前の静けさ 夜明け前 激動の予感
15	2017	Biology Based Diagnosis and Treatment

**Primary Treatment of Early Breast Cancer St. Gallen 2017**

**Escalating and De-Escalating Treatment in Early Breast Cancer across Subtypes and Treatment Modalities**

*Consensus & Controversy*



**早期乳がん (Early Breast Cancer) 初期治療 (Primary Treatment) の選択肢 2017~**

- **治療順位**
  - 局所療法 → 全身療法
  - 全身療法 → 局所療法
  - 全身療法 → (局所療法) → 全身療法
- **病型別治療**
  - IHCでの分類を基本とする考え方
  - 多遺伝子発現解析を基本とする考え方
- **全身治療手段**
  - 非選択的治療 = 細胞毒性抗がん剤
  - 選択的薬物療法 = 内分泌 + 抗HER2 + 他の標的治療
  - 駆動遺伝子 (ドライバージーン) 対応治療

**早期乳がん (Early Breast Cancer) 初期治療 (Primary Treatment) の選択肢 1970年代**

- **治療** = ハルステッド手術
- **病型分類** = そういものは存在しない
- **全身治療手段** = そういものは存在しない

**早期乳がん (Early Breast Cancer)  
初期治療 (Primary Treatment) の選択肢**

**20xx 年**

- **治療**
  - 手術は検査
  - 全身療法 = 薬物療法
- **病型別治療**
  - 多遺伝子発現解析に基づく分類
- **全身治療手段**
  - 駆動遺伝子 (ドライバー遺伝子) 対応治療

**St.Gallen Oncology Web Site**  
<http://www.oncoconference.ch/>

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**St.Gallen-2017: The Major National Contingents out of 105 Countries (as of March 14, 2017)**

1. Austria (259)	11. Sweden (56)
2. Switzerland (257)	12. Poland (55)
3. P.R. of China (222)	13. Netherlands (48)
4. Germany (195)	14. Australia (47)
5. USA (187)	15. Israel (43)
6. Italy (128)	16. Greece (41)
7. Japan (111)	17. Czech Republic (36)
8. United Kingdom (88)	18. Denmark (35)
9. Belgium (70)	19. Turkey (35)
10. South Korea (59)	20. Russia (34)

Underlined: Countries with rising attendance!

**St.Gallen Oncology Web Site**  
<http://www.oncoconference.ch/>

**St.Gallen-2015: The Major National Contingents out of 135 Countries (as of March 10, 2015) to be updated**

1. Switzerland (263)	11. Sweden (65)
2. China, incl. Hongkong (242)	12. Greece (54)
3. Austria (195)	13. Egypt (48)
4. Germany (165)	14. Australia (45)
5. Japan (153)	15. Indonesia (42)
6. Italy (123)	16. Israel (41)
7. USA (114)	17. South Korea (40)
8. Belgium (78)	18. Argentina (37)
9. United Kingdom (69)	19. Canada (33)
10. Poland (66)	20. The Netherlands (31)

St.Gallen-2013: The Major National Contingents out of 104 Countries	2013	St.Gallen-2015: The Major National Contingents out of 135 Countries	2015
1. Switzerland (670)	11. Indonesia (56)	1. Switzerland (263)	11. Sweden (65)
2. China (282)	12. Greece (53)	2. China, incl. Hongkong (242)	12. Greece (54)
3. Germany (262)	13. India (49)	3. Austria (195)	13. Egypt (48)
4. Japan (252)	14. Argentina (48)	4. Germany (165)	14. Australia (45)
5. United Kingdom (128)	15. Israel (47)	5. Japan (153)	15. Indonesia (42)
6. Austria (126)	16. Netherlands (47)	6. Italy (123)	16. Israel (41)
7. USA (102)	17. Singapore (40)	7. USA (114)	17. South Korea (40)
8. Italy (84)	18. Korean Republic (38)	8. Belgium (78)	18. Argentina (37)
9. Belgium (80)	19. Poland (37)	9. United Kingdom (69)	19. Canada (33)
10. Sweden (63)	20. Russian Fed. (36)	10. Poland (66)	20. The Netherlands (31)

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Underlined: Countries with rising attendance!

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初期治療 (Primary Treatment) の選択肢**

- **治療順位**
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And Now: What is Different About the AJCC 8<sup>th</sup> Edition?

2010-2017 vs 2018 and Beyond

Christy Russell, USA

Genomic Health

Oncotype DX Recurrence Score <11 Can Result in Lower Stage than Would Be Recorded Using Biologic and Anatomic Factors Alone

6<sup>th</sup> ed. Pragmatic Stage using TNM, grade, ER, PgR, HER2

5<sup>th</sup> ed. Pragmatic Stage using TNM, grade, ER, PgR, HER2

4<sup>th</sup> ed. Pragmatic Stage using TNM, grade, ER, PgR, HER2

3<sup>rd</sup> ed. Pragmatic Stage using TNM, grade, ER, PgR, HER2

2<sup>nd</sup> ed. Pragmatic Stage using TNM, grade, ER, PgR, HER2

1<sup>st</sup> ed. Pragmatic Stage using TNM, grade, ER, PgR, HER2

Christy Russell, USA

Genomic Health

Escalating and De-escalating

**APPROPRIATE MARGINS IN PRIMARY SURGERY AND IN SURGERY FOLLOWING NEOADJUVANT SYSTEMIC THERAPY**

DCIS症例に乳房温存手術+全乳房照射を行う場合 再切除を不要にするための十分なマージンは？

1. No ink on DCIS
2. 2 mm
3. 5 mm
4. 断端はこだわらない
5. 棄権

棄権 4%

no ink on DCIS 35%

2mm 62%

Journal of Clinical Oncology

Society of Surgical Oncology–American Society for Radiation Oncology–American Society of Clinical Oncology Consensus Guideline on Margins for Breast-Conserving Surgery With Whole-Breast Irradiation in Ductal Carcinoma In Situ

DOI: 10.1200/JCO.2016.68.3573  
PMID: 27528719

術前薬物療法後、浸潤がん手術→照射の場合； Surgery of the Primary (IDC) after Neoadjuvant Systemic Therapy

ダウンスタージ後に原発巣の全領域を切除するべきか？ Should the entire area of the original primary be resected after downstaging?

1. はい
2. いいえ
3. 棄権

棄権 3.6%

はい 14.3%

いいえ 82.1%



Escalating and De-escalating

**WHEN CAN AXILLARY SURGERY BE REDUCED?**

JOURNAL OF CLINICAL ONCOLOGY ASCO SPECIAL ARTICLES

**Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update**  
David W. Tan, David A. Asch, David J. Slamon, Charles E. Hudis, Susan C. Harlow, and Charles I. Hudis

**Objective:** Current recommendations in the use of sentinel lymph node (SLN) biopsy for patients with early-stage breast cancer were updated to reflect the most recent evidence.

**Methods:** A panel of experts convened to review and update the clinical practice guideline. The panel members conducted a systematic review of the literature and developed recommendations based on the evidence.

**Results:** The panel concluded that SLN biopsy is a reasonable approach for patients with early-stage breast cancer. The panel also recommended that SLN biopsy be performed in patients with early-stage breast cancer who are being treated with breast-conserving therapy.

**Conclusion:** The panel concluded that SLN biopsy is a reasonable approach for patients with early-stage breast cancer. The panel also recommended that SLN biopsy be performed in patients with early-stage breast cancer who are being treated with breast-conserving therapy.

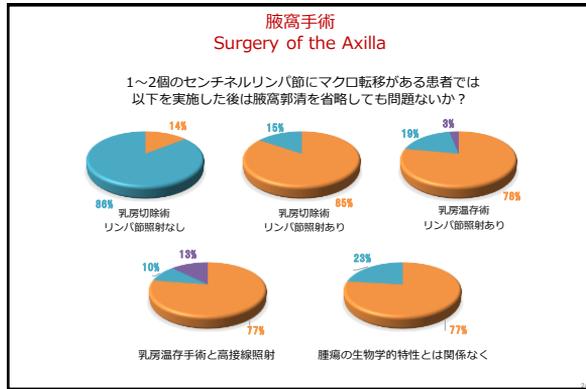
DOI: 10.1200/JCO.2016.71.0947  
PMID: 27937089

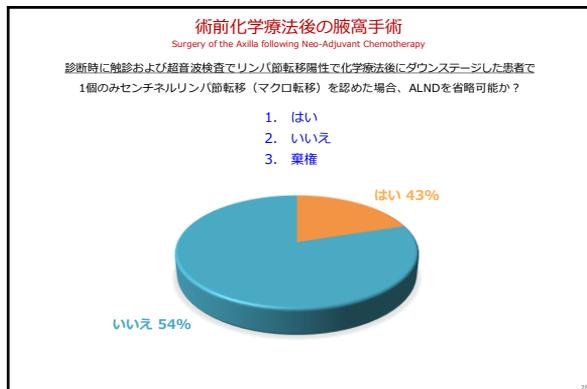
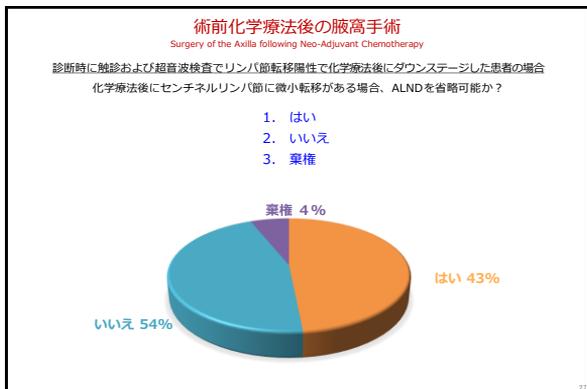
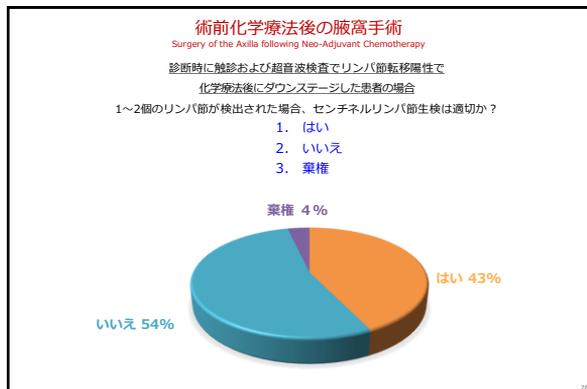
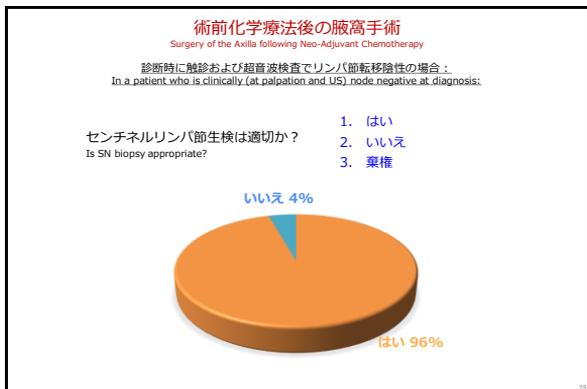
**腋窩手術**  
Surgery of the Axilla

1~2個のセンチネルリンパ節にマクロ転移がある患者では以下を実施した後は腋窩郭清を省略しても問題ないか?

In patients with macro-metastases in 1-2 sentinel nodes, completion of axillary dissection can safely be omitted following.

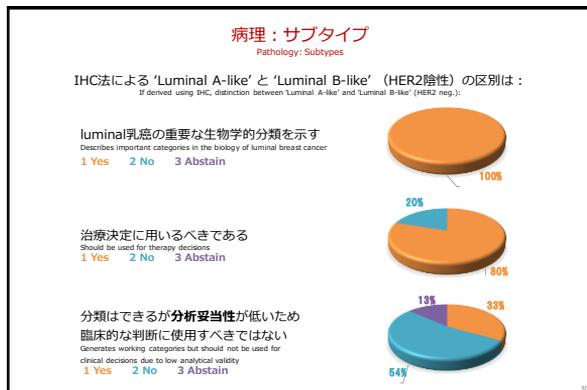
乳房切除術 (リンパ節への放射線療法を予定なし) Mastectomy (w/ radiotherapy to lymph nodes planned)	1 Yes	2 No	3 Abstain
乳房切除術 (リンパ節への放射線療法を予定) Mastectomy (w/ radiotherapy to lymph nodes planned)	1 Yes	2 No	3 Abstain
乳房温存手術と標準的な再接線照射による放射線療法 Conservative resection with radiotherapy using standard tangents	1 Yes	2 No	3 Abstain
乳房温存手術と高接線照射による放射線療法 Conservative resection with radiotherapy using high tangents	1 Yes	2 No	3 Abstain
腫瘍の生物学的特性 (ER陽性、ER陰性、Grade 3など) とは関係なく Irrespective of tumor biology (LV, ER, grade 3 etc.)	1 Yes	2 No	3 Abstain

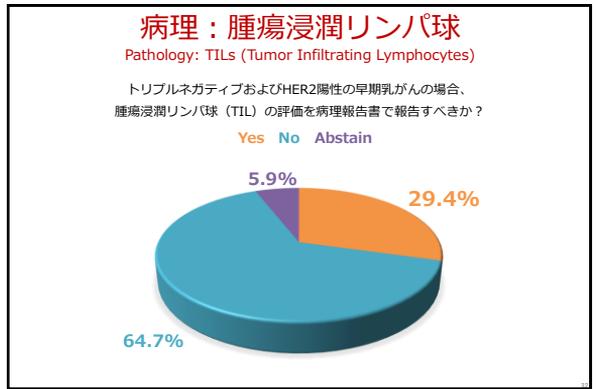
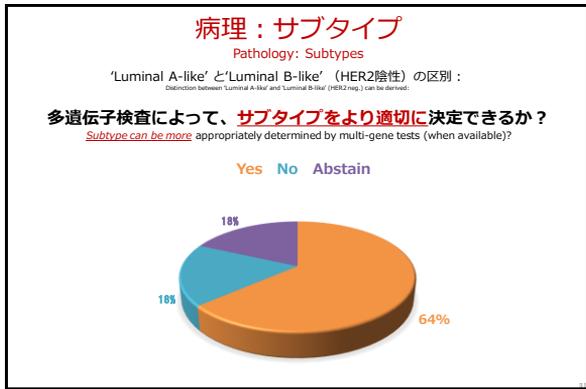




Escalating and De-escalating

**WHEN IS TRADITIONAL PATHOLOGY (STAGE, GRADE, LVI, ER/PR/HER2) NOT INFORMATIVE ENOUGH?**



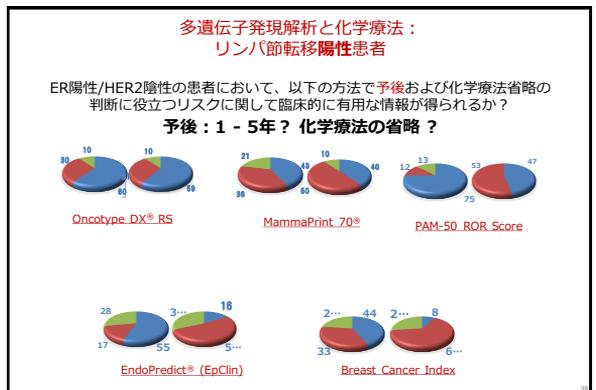
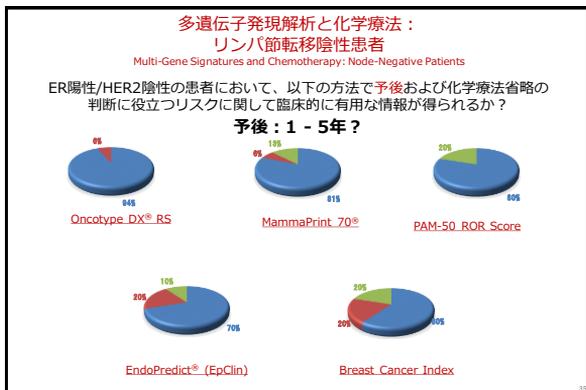
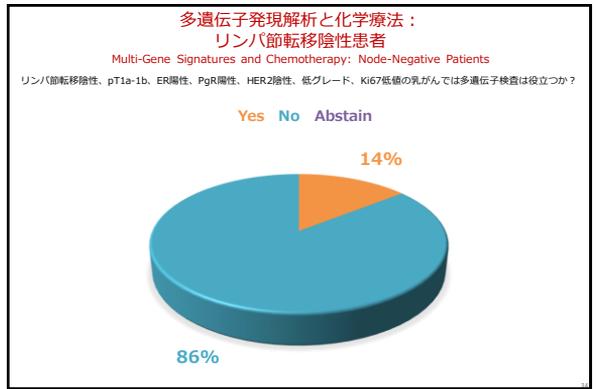


### 検査の意義を判断するための3つのステップ

**Analytical validity (分析方法の信頼性)**  
適切な検体を用いて同じ方法を用いれば、異なった時、異なった人、異なった検査室で実施しても同じ結果が得られる

**Clinical validity (臨床的信頼性)**  
臨床的に明確に定義された病態を的確(accurate)かつ正確 (precise) に同定することができる

**Clinical utility (臨床的有用性)**  
正しい臨床判断を導き、その検査を利用すると利用しない場合と比べ診療結果が向上する



Escalating and De-escalating

### WHICH WOMEN SHOULD RECEIVE OVARIAN SUPPRESSION AS ADJUVANT ENDOCRINE THERAPY?

内分泌療法 閉経前患者  
治療の選択

以下の臨床病理学的特性は卵巣機能抑制（OFS）の適応を考慮する因子となるか？

35歳未満

術後化学療法後にエストロゲン値が閉経前レベル

リンパ節転移4個以上

内分泌療法  
閉経前患者（エストロゲン、FSHおよびLHで評価）

患者によってはOFS+AIを使用すべきか？

Yes No Abstain

内分泌療法 閉経後患者

TAM単剤療法が適している患者もいるか？  
Is Tamoxifen alone still appropriate for some pts?

Yes No Abstain

内分泌療法 閉経後患者

いずれかの時点でAIを追加する根拠は何か？  
Parameters for inclusion of an AI at some point are:

Yes No Abstain

閉経後の全患者: 51% Yes, 45% No, 4% Abstain

リンパ節転移陽性: 86% Yes, 14% No, 0% Abstain

Grade 3 またはKi67高値: 81% Yes, 17% No, 2% Abstain

HER2陽性: 62% Yes, 34% No, 4% Abstain

内分泌療法 閉経後患者

AIを用いるなら最初から用いたほうが良い患者は？  
If an AI is used, should it be started upfront:

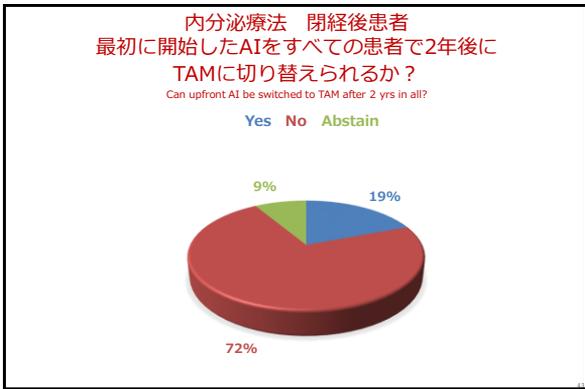
Yes No Abstain

あらゆる患者: 56% Yes, 40% No, 4% Abstain

一部の患者: 98% Yes, 2% No, 0% Abstain

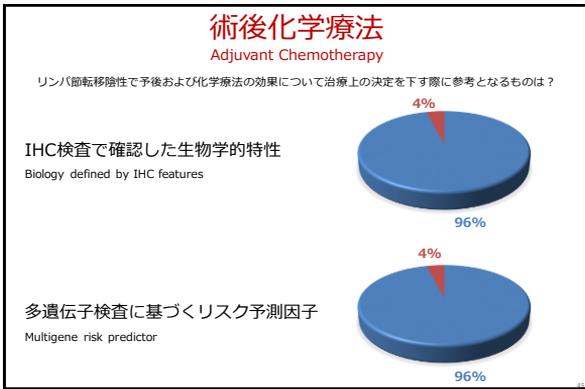
高リスクの患者: 94% Yes, 6% No, 0% Abstain

小葉がんの患者: 78% Yes, 14% No, 8% Abstain



Escalating and De-escalating

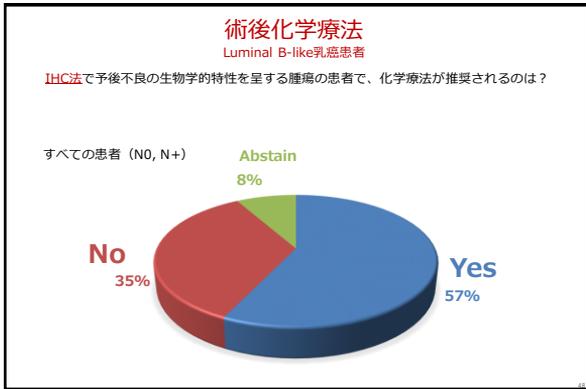
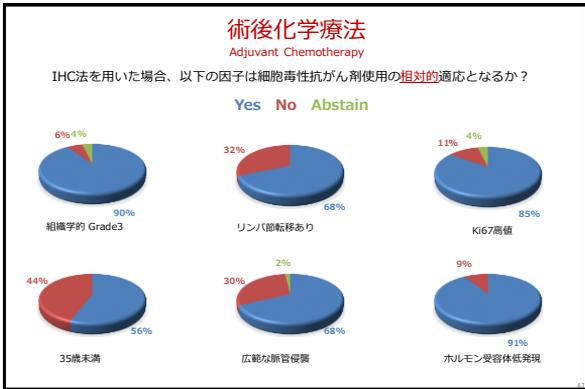
**WHICH WOMEN SHOULD RECEIVE ADJUVANT CHEMOTHERAPY?**

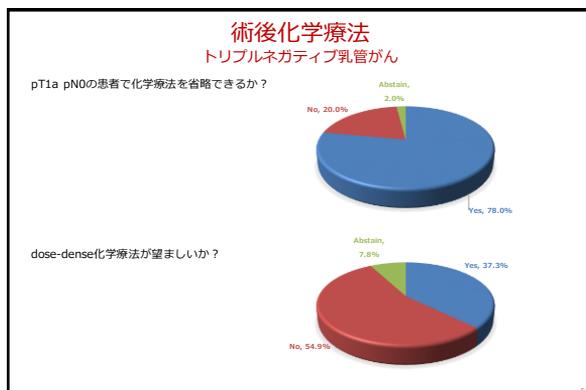
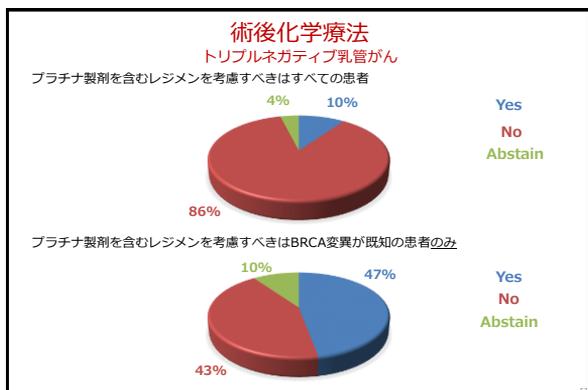
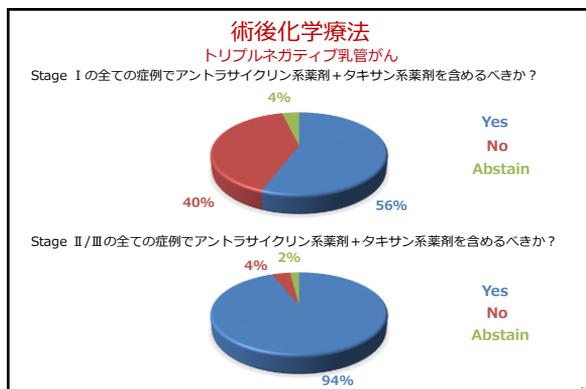
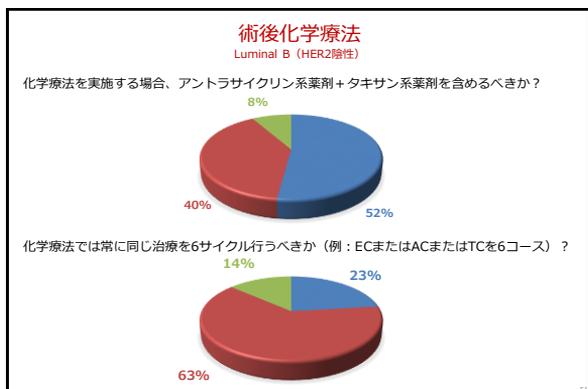
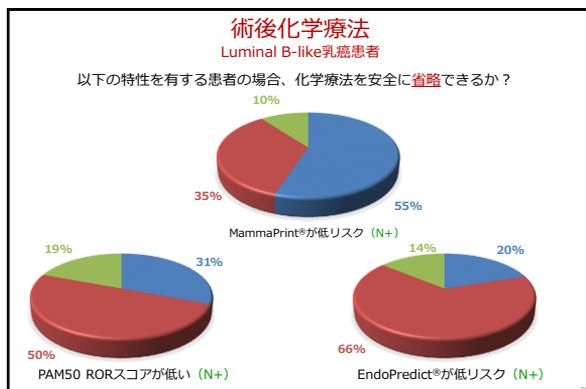
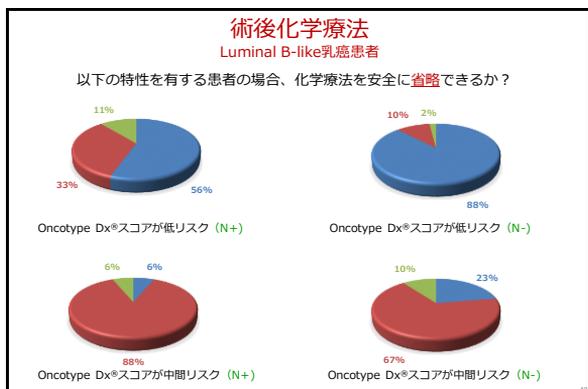


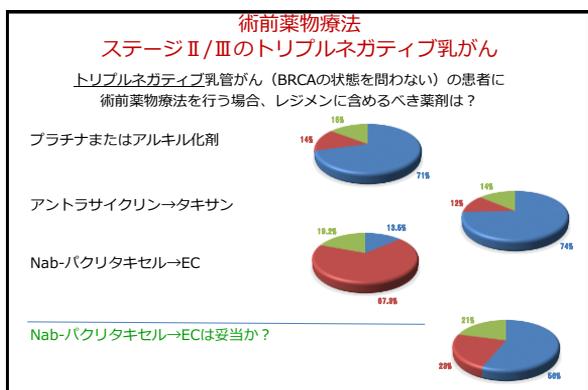
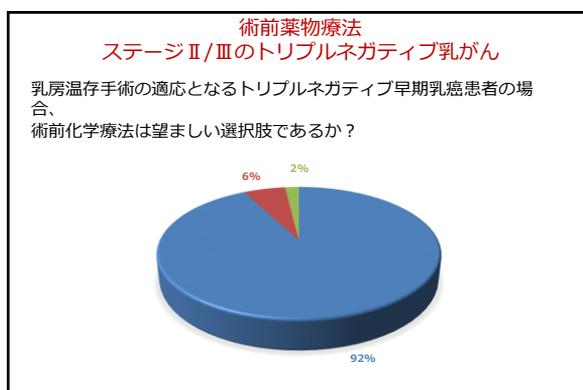
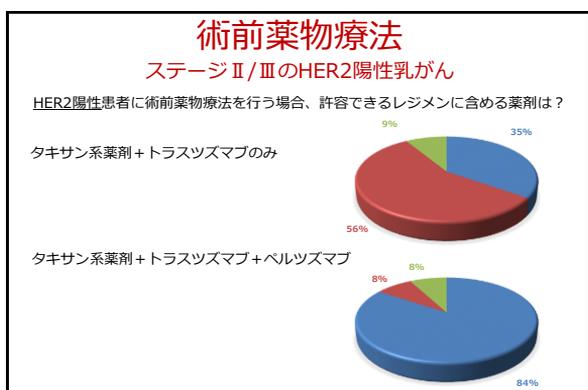
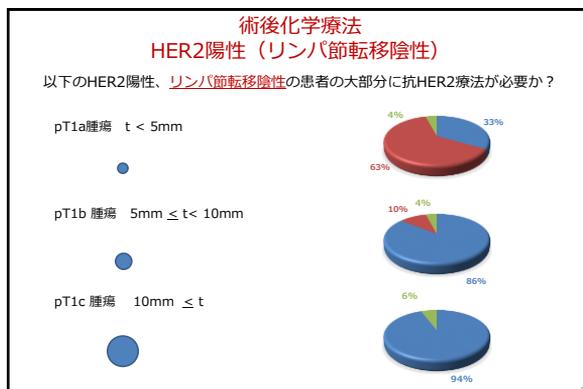
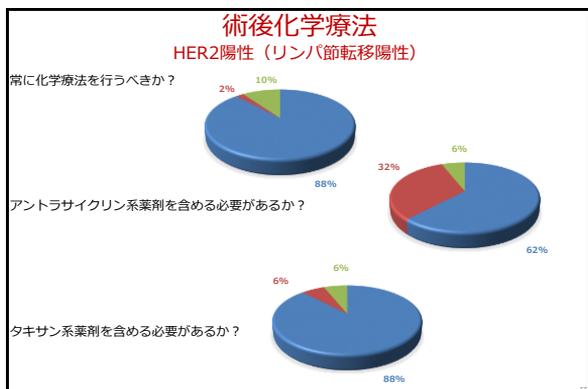
**術後化学療法**

IHC法を用いた場合、以下の因子は細胞毒性のある術後化学療法の相対的適応となるか？

- 組織学的Grade3
- リンパ節転移あり
- 35歳未満
- 広範な脈管侵襲
- ホルモン容体低発現







- ### 印象とまとめ
1. 術前薬物療法が「ばば標準」となってきた
  2. ANATOMY (MORPHOLOGY, PATHOLOGY)から BIOLOGY, GENOMICSへの流れが本格化している
  3. 検査にはANALYTICAL VARIETY, CLINICAL VARIETY, CLINICAL UTILITY が求められる
  4. 臨床試験・臨床研究結果を発信していかないと全く相手にされない（以前からそうだったが益々の傾向）
  5. 討論も結構楽しくできる雰囲気である
  6. 若い人々にも積極的に海外に羽ばたいてもらいたい