Non-Muscle-Invasive Bladder Cancer

Staging, Treatment and Assessment
Featuring SWOG Trials S1602 & S1605

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S1605 Study Chair
University of British Columbia – Vancouver Prostate Centre

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Estimated New Cases*

Male	Female
Prostate 220,800 (26%)	Breast 231,840 (29%)
Lung & bronchus 115,610 (14%)	Lung & bronchus 105,590 (13%)
Colon & rectum 69,090 (8%)	Colon & rectum 63,610 (8%)
Urinary bladder 56,320 (7%)	Uterine corpus 54,870 (7%)
Oral cavity & pharynx 32,670 (4%)	Pancreas 24,120 (3%)
Leukemia 30,900 (4%)	Leukemia 23,370 (3%)
Liver & intrahepatic bile duct 25,510 (3%)	Kidney & renal pelvis 23,290 (3%)
All sites 848,200 (100%)	All sites 810,170 (100%)

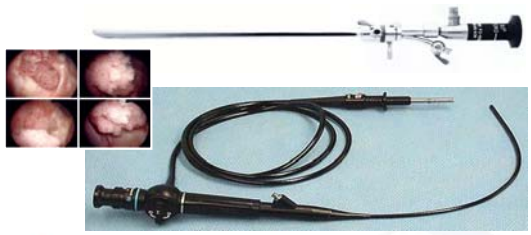
- #5 cancer overall in Canada (8,000) and U.S (74.000)
- prevalence > 500,000
- most-expensive cancer in lifetime of patient

Urinary Bladder 17,680 (#12)

American Cancer Society 2015

SWOG Leading

The Gold Standard for Bladder Cancer Detection



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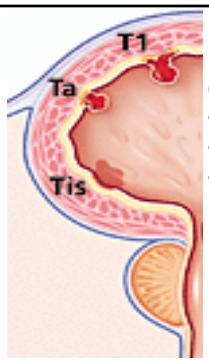

Non-muscle invasive bladder cancer:

- preserve bladder
- TURBT
- intravesical chemo/BCG

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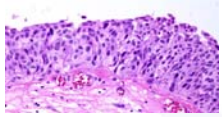
Carcinoma in situ

- non-invasive, flat, and high-grade cancerous lesion confined to the mucosa



- highly malignant and potentially aggressive
- primary – secondary - concurrent

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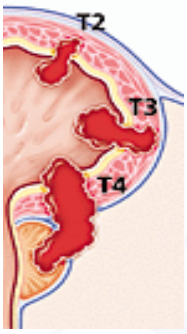
Muscle invasive bladder cancer:

- remove bladder (cystectomy)
- pre-operative chemo (=neo-adjvuant)
- rarely radiation



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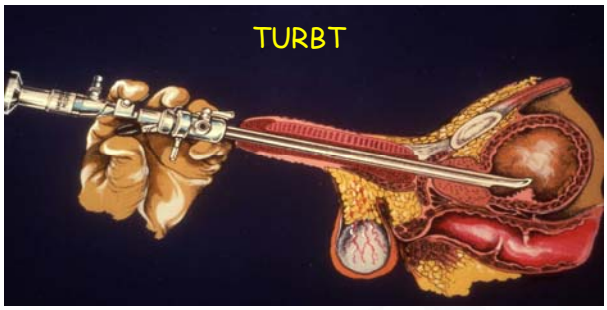

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Risk stratification in NMIBC

LOW RISK	INTERMEDIATE RISK	HIGH RISK
single low grade <3cm first occurrence incl. PNLMP (50%)	everything else: multifocal recurrent >3cm low grade (35%)	any high grade any T1 CIS (15%)

- **low risk: <5% progress, 40-50% recur**
- **high risk: 30% progress, 70-80% recur**

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Importance of re-TURBT

- Removes residual disease
- Identifies understaging
- Improves results of intravesical therapy
- Important risk stratification

AUA Guidelines:

Re-TUR mandatory for all T1 tumors in the absence of muscle (Grade A)

Re-TUR is recommended for T1 even if benign muscle present (Grade C)

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Risk adapted NMIBC Therapy

Low Risk

- TURBT + single dose post-op chemo
- office fulguration
- observation/follow-up

Intermediate Risk

- TURBT + single dose post-op chemo
- consider adjuvant chemo, *or* BCG with maintenance (1 year)

High Risk

- TURBT + BCG with maintenance (3 years)
- consider cystectomy

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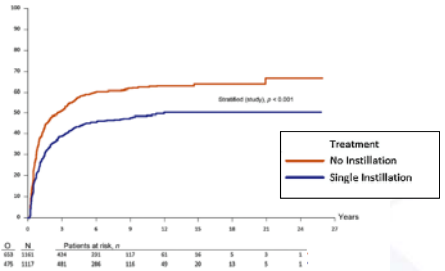
Single Dose Post-operative Chemo



Sylvester et al., Eur Urol 2016

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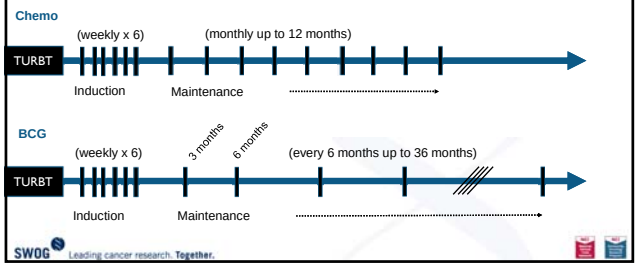
Adjuvant intravesical therapy



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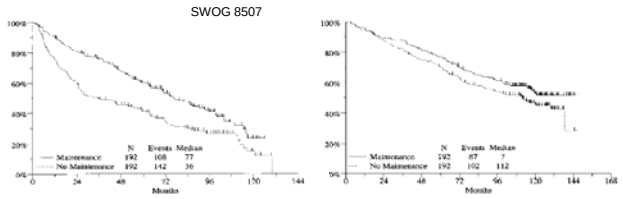
BCG Induction + Maintenance



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Lamm et al., J Urol 2000

Avoid premature stop of BCG

- **primary CIS** in SWOG 8507
- maintenance vs. no maintenance
  - 3 month disease free 55% vs. 57%
  - 6 month disease free 84% vs. 68%
- conclusions:
  - BCG maintenance is necessary
  - delayed response common after first round of maintenance
  - re-evaluate with bladder biopsy at 6 month time-point

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Lamm et al., J Urol 2000

CLINICAL TRIAL

S1602 in BCG-naïve high risk patients

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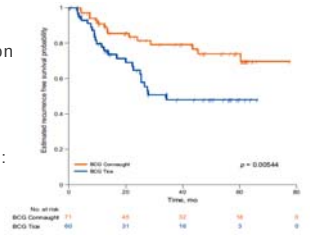
Bacillus Calmette-Guérin Strain Differences Have an Impact on Clinical Outcome in Bladder Cancer Immunotherapy

Cyrill A. Rentsch[a,b,i], Frédéric D. Birkhäuser[c,i], Claire Biot[b,d,e,i], Joël R. Gsponer[a,b,i], Aurélie Bisiaux[b,d], Christian Wetterauer[a,b,i], Micheline Logranderie[f], Gilles Marchal[f], Mickael Orgeur[g], Christiane Bouchier[g], Alexander Bachmann[a], Molly A. Ingersoll[b,d], Roland Brosch[g], Matthew L. Albert[b,d,i,j,i], George N. Thalmann[a,i,*]

EUROPEAN UROLOGY 66 (2014) 677–688

- 149 pts with high risk NMIBC
- randomized to 6-week induction of ImmuCyst (Connaught) vs OncoTice
- median f/u 25 months
- ImmuCyst superior to Oncotice:
  - 5-yr RFS 75% vs 48% (p=0.01)
  - 5-yr PFS 95% vs 87% (p=0.059)
  - no survival difference



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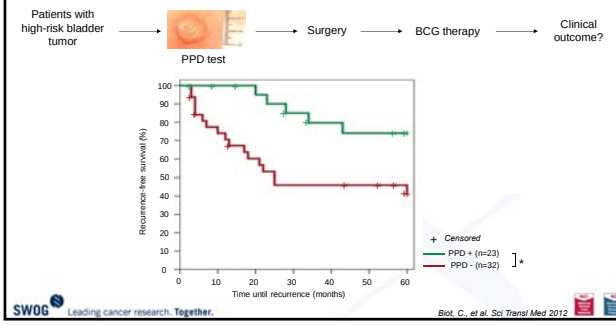
Pre-existing BCG-specific immunity improves anti-tumor response in patients



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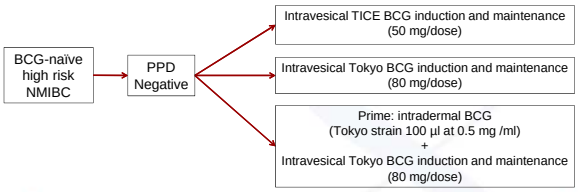
Biot, C., et al. Sci Transl Med 2012

SWOG 1602 (PRIME)

A Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer



PI: Robert Svatek, UT San Antonio

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TREATMENT FOR RECURRENCE AFTER BCG

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"BCG unresponsive NMIBC"

- Any high grade recurrence after induction + 1st round maintenance, or 2 rounds induction
  - ***Exception***: high grade T1 disease at 3 months (after induction BCG only) is considered "unresponsive"
- For patients who achieve complete response on induction/maintenance BCG:
  - any high grade Ta/T1 within 6 months, or
  - any CIS within 12 months of last dose of BCG
- Recurrent low grade Ta disease is not considered unresponsive in this context

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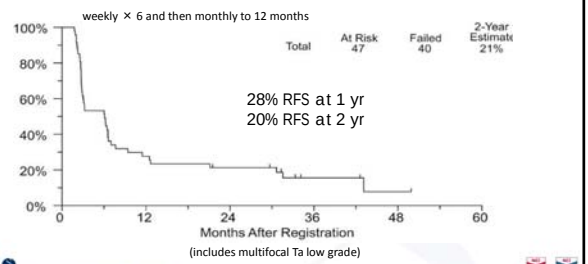
SWOG S0353 Phase II trial of intravesical gemcitabine for BCG unresponsive NMIBC



Skinner et al, J Urol, 2013

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CLINICAL TRIAL

S1605 in BCG-unresponsive patients

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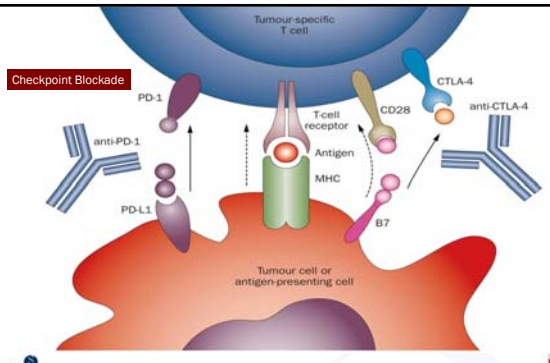

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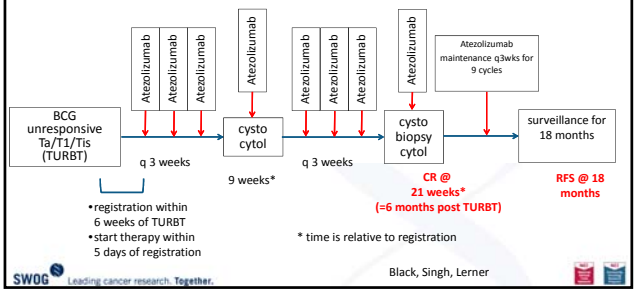
[Checkpoint Inhibitor]

S1605: Phase 2 trial of Atezolizumab in BCG-unresponsive NMIBC



Black, Singh, Lerner

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Co-Primary Endpoints

1. Complete response (CR) in patients with CIS
   - negative cytology, cystoscopy, biopsy at 6 months
2. Event-free survival (EFS) at 18 months for overall study cohort (Ta/T1/CIS)
   - event = any high grade tumor or any metastasis

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Diving into S1602

Joseph Sanchez
S1602 Data Coordinator
SWOG Statistics and Data Management Center

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Write it down

- Contact us! **S1602Question@swog.org**
- CIS patients must have a biopsy at 180 (+/- 10) days from registration
- Perform PPD tests at Pre-Study, Month 3, and Month 6 until the test is positive
- If it has a date field and a source documentation form in the folder, submit the source documentation. We want everything!

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Diving into the forms

- **Onstudy**:
  - If patient has *ever* had T1 or Ta, check T1 or Ta. The more stringent eligibility criteria applies.
  - Submit all of the source documentation.
- **PPD testing**:
  - A form of its own with great expectations
  - Take a picture! But don't send it to us.
  - Time to read must be 48-72 hours

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Even deeper into the forms

- **Treatment + AE forms**
  - Not actually due until 30 days into the next cycle
  - There is no Month 9 BCG treatment
- **Disease Assessment form**
  - 180 day biopsy for CIS patients
  - We want all of the source documentation
- **Follow Up**
  - Off treatment at same time points as Disease Assessments, but continuing even after HGR

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The bottom of the forms

- The Comments section
- Contact us! **S1602Question@swog.org**

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S1605 – *Protocol & Data Submission Requirements*

Sean O'Bryan
S1605 Data Coordinator
SWOG Statistics and Data Management Center

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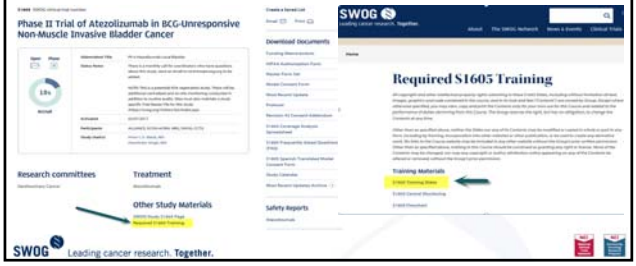
Training on S1605

How to get to Training materials for S1605:

- CRA Workbench → SWOG Protocols → S1605 → Required 1605 Training



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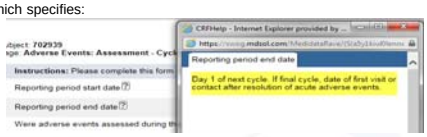
Treatment & AE Assessments on S1605

- Treatment cycles are 21 days long (for a maximum of 17 cycles/51 weeks) and are administered Intravenously on the 1st day of the cycle.
- Atezolizumab tx may be administered up to three days before or after the protocol specified dose administration date, each 21 day cycle, due to administrative reasons.
- Atezolizumab is administered as an intravenous infusion over 60 minutes.
  - If the first infusion is tolerated, all subsequent infusions may be delivered over 30 minutes.
- For AE Assessments, please refer to the help box feature in RAVE, next to "reporting period end date", which specifies:



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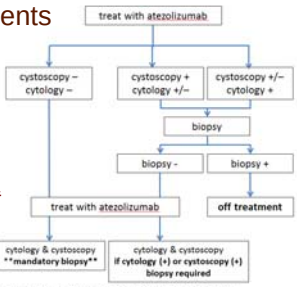
Disease Assessments on S1605



Reminder to submit ALL reports for each assessment period.

This includes:

Cystoscopy report, Cytology report, & Biopsy OP / PATH reports (if done)

- Positive cystoscopy is defined as suspicious for malignancy
- Positive cytology is defined as positive for malignant cells
- Disease assessment schedule is independent of treatment schedule. Disease assessment must occur at weeks 13 & 25 (± 7 days) regardless of treatment delays.

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Protocol Updates/Amendments

- A recent memo came out that specified new information regarding specimen submissions (as shown below):

S1605 laboratory kits containing the Smart reagent (PROT1) are now available for ordering. The whole blood specimens noted in Section 15.1.a.2.b. (whole blood collected on Day 1 of Cycles 1, 5, 9 and 17) must be submitted and processed per the instructions provided in the kit.

Note: The **Cycle 1 specimen** is required for submission of downstream specimens. If a Cycle 1 blood specimen processed with the provided PROT1 buffer has not been submitted, then sites should not submit follow-up whole blood PROT1 specimens.

It is preferred that kits are ordered for registered patients only, because these are uncommon reagents being used for this study and waste should be prevented. If sites can order before noon Eastern, then they should receive the kits 3 – 4 business days after the request, if not sooner.

The kits should be ordered in enough time to receive them prior to baseline collection and can be ordered online at:

https://ncappa.nationwidechildrens.org/KitManagement

The baseline whole blood specimen noted in Section 15.1.a.2.a (5 mL whole blood in sodium-heparin tube) should be submitted in a SODIUM **CITRATE** TUBE. This correction will be made in the protocol in the next upcoming amendment.

- Inclusion criteria w/ respect to timing of last BCG dose: We would like last BCG within 6 months of recurrence.
- Pure squamous carcinoma in situ will be excluded

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FAQ's/Important Information for S1605

- T1 Patients must undergo a re-TURBT within 60 days of registration and must submit OP & PATH reports from both the original TURBT and re-TURBT.
  - If the re-TURBT was done was done within 21 days of registration and the cystoscopy was done during that re-TURBT, then you do not need to do a repeat cystoscopy.
- Treatment can continue when awaiting test results from disease assessments (cytology, cystoscopy, biopsy).
- The specimens & reports mentioned in Section 12 are mandatory and must be submitted at the required time-points, primarily for CIS patients.
  - Please note: The Urine Cytology slide mentioned in Section 12 does not need to be submitted at baseline, however the Cytology report done at baseline should be submitted instead.
- All other specimens mentioned in Section 15 of the protocol are optional, unless the patient consents.
- Patients with positive cytology or suspicious cystoscopy at any of the scheduled time points of assessment during the trial must have a biopsy, per standard of practice.

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FAQ's/Important Information for S1605

- Allowable windows for scheduled disease assessments performed every 12 weeks is +/- 7 days, every 24 weeks is +/- 7 days
  - The window is to be calculated from the scheduled date of the procedure/assessment
- Carcinoma in situ is by definition high grade
- Required Follow Up Safety Assessment @ 30 & 90 days after last dose of tx:
  - If the patient experienced any adverse event (any grade) in the first 30 days following completion/discontinuation of treatment that is possibly, probably or definitely related to protocol treatment that has not been previously reported, please report in the ***Late Effects Form***. After the first 30 days following completion/discontinuation of treatment, *only severe (grade ≥ 3)* adverse events that are possibly, probably or definitely related to protocol treatment that have not been previously reported are required to be reported here.

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Contacts for S1605

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Elaine Armstrong, Quality Assurance/Audits Manager
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Emails: ntrevino@swog.org / earmstrong@swog.org / kwilliams@swog.org

Lab #201 SWOG Specimen Repository:
Solid Tissue, Myeloma & Lymphoma Division
Nationwide Children's Hospital
Phone: 614-722-2865
Email: bpcbank@nationwidechildrens.org

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SWOG FDA Registration Trials

Melissa Plets
Biostatistician
SWOG Statistics and Data Management Center

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What makes FDA registration trials so…

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1) Traceability

2) Data Quality

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Outline

- Database
  - Title 21 CFR **Part 11**
- Data Collection
  - CDISC
- Changes to SWOG standard CRFs
- New CRFs
- Increasing data quality
  - Risk-based monitoring
  - Reports

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Database

Title 21 of the Code of Federal Regulations, Part 11:

The Food and Drug Administration (FDA) guidelines …considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be **trustworthy**, **reliable**, and **generally equivalent to paper records** and **handwritten signatures** executed on paper.

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Database

- Access to data is limited
- Any changes are carefully documented and approved, no matter how minor the change may be.
  - Structural changes documented via a Change Control document.
  - Data changes documented by the DC using a Data Change Request.

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Data collection

- Traceability of all data in analyses back to specific CRFs
  - **Last Contact Date** from CRFs (pts on multiple studies)
    Must be **UNIQUE** patient ID: 7*****
    - Non-reg study ➔ FDA reg study
    - FDA reg study ➔ Non-reg study
    - FDA reg study ➔ FDA reg study

- Cross-form consistency
  - SAE and AE data
  - Patient is off due to progression (Off Treatment Form), but does not have documentation of progressive disease
- CDASH forms prospectively

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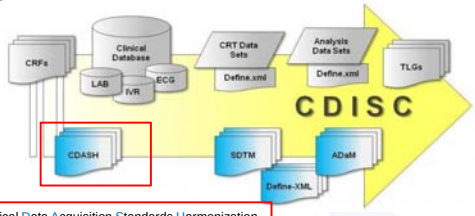
Clinical Data Interchange Standards Consortium (CDISC)



- Clinical Data Acquisition Standards Harmonization
- Study Data Tabulation Model
- Analysis Data Model

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NCI vs FDA

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Changing SWOG CRF standards:
Ask once

VITAL STATUS

Vital status: ☐ Alive ☐ Dead *(submit Notice of Death)* **Date of last contact:** ☐☐ / ☐☐ / ☐☐☐☐

~~If dead, date of death: ☐☐ / ☐☐ / ☐☐☐☐~~

SWOG
NOTICE OF DEATH

Patient Identifier ☐☐☐☐☐ **Study Identifier** S☐☐☐☐

Patient Initials _____ (L, F M)

Registering/Treating Institution _____ / _____ Physician _____

Participating Group: Group Name/Study No./Patient ID _____ / _____ / _____

Instructions: Answer all questions and explain any blank fields or blank dates in the **Comments** section. Place an [X] in appropriate boxes.

OUTCOME MEASURES

Date of Death: ☐☐ / ☐☐ / ☐☐☐☐ (month / day / year)

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Changing SWOG CRF standards:
Missing disease assessment data

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Changing SWOG CRF standards:
Missing disease assessment data

DISEASE ASSESSMENT

Was a cystoscopy performed? ☐Yes ☐No **Cytoscopy date:** ☐☐ / ☐☐ / ☐☐☐☐

If No, **Specify why:** _____

If Yes, **Suspicious findings?:** ☐Yes ☐No

If Yes, check all that apply:

☐Low grade papillary tumor ☐CIS

☐High grade papillary tumor ☐Other, please specify: _____

Was cytology done? ☐Yes ☐No **Date:** ☐☐ / ☐☐ / ☐☐☐☐

If No, **Specify why:** _____

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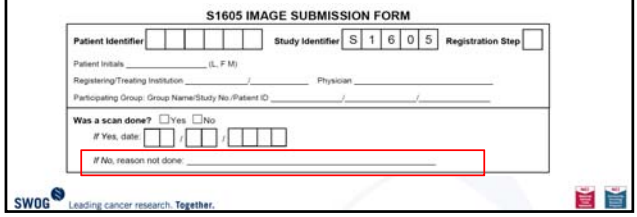
Collection of Scan Images (CT/MRI)

- Upload the images (AG Mednet, IROC/TRIAD)
- Submitting scan reports as source docs in Rave



S1605 IMAGE SUBMISSION FORM

Patient Identifier ☐☐☐☐☐☐ Study Identifier S 1 6 0 5 Registration Step ☐

Patient Initials _____ (L, F M)

Registering/Treating Institution _____/_____ Physician _____

Participating Group: Group Name/Study No./Patient ID _____/_____/_____

Was a scan done? ☐Yes ☐No

If Yes, date: ☐☐/☐☐/☐☐☐☐

If No, reason not done: _____

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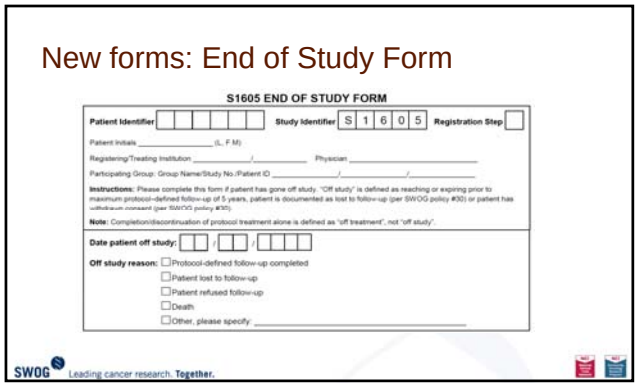
New forms: End of Study Form



S1605 END OF STUDY FORM

Patient Identifier ☐☐☐☐☐☐ Study Identifier S 1 6 0 5 Registration Step ☐

Patient Initials _____ (L, F M)

Registering/Treating Institution _____/_____ Physician _____

Participating Group: Group Name/Study No./Patient ID _____/_____/_____

Instructions: Please complete this form if patient has gone off study. "Off study" is defined as reaching or expiring prior to maximum protocol-defined follow-up of 5 years, patient is documented as lost to follow-up (per SWOG policy #30) or patient has withdrawn consent (per SWOG policy #35).

Note: Completion/discontinuation of protocol treatment alone is defined as "off treatment", not "off study".

Date patient off study: ☐☐/☐☐/☐☐☐☐

Off study reason: ☐Protocol-defined follow-up completed
☐Patient lost to follow-up
☐Patient refused follow-up
☐Death
☐Other, please specify: _____

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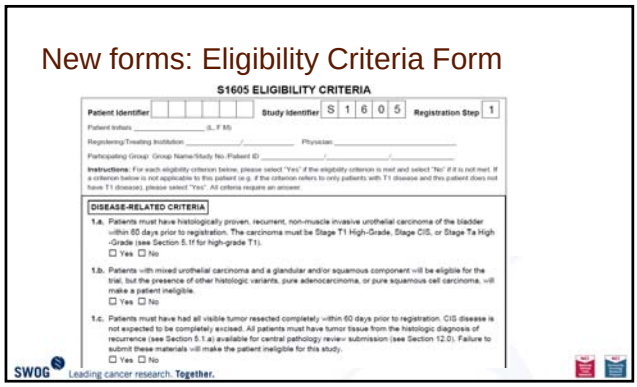
New forms: Eligibility Criteria Form



S1605 ELIGIBILITY CRITERIA

Patient Identifier ☐☐☐☐☐☐ Study Identifier S 1 6 0 5 Registration Step 1

Patient Initials _____ (L, F M)

Registering/Treating Institution _____/_____ Physician _____

Participating Group: Group Name/Study No./Patient ID _____/_____/_____

Instructions: For each eligibility criterion below, please select "Yes" if the eligibility criterion is met and select "No" if it is not met. If a criterion below is not applicable to this patient (e.g. if the criterion refers to only patients with T1 disease and this patient does not have T1 disease), please select "Yes". All criteria require an answer.

DISEASE-RELATED CRITERIA

1.a. Patients must have histologically proven, recurrent, non-muscle invasive urothelial carcinoma of the bladder within 60 days prior to registration. The carcinoma must be Stage T1 High-Grade, Stage CIS, or Stage Ta High-Grade (see Section 5.1f for high-grade T1).
☐Yes ☐No

1.b. Patients with mixed urothelial carcinoma and a glandular and/or squamous component will be eligible for the trial, but the presence of other histologic variants, pure adenocarcinoma, or pure squamous cell carcinoma, will make a patient ineligible.
☐Yes ☐No

1.c. Patients must have had all visible tumor resected completely within 60 days prior to registration. CIS disease is not expected to be completely excised. All patients must have tumor tissue from the histologic diagnosis of recurrence (see Section 5.1.a) available for central pathology review submission (see Section 12.0). Failure to submit these materials will make the patient ineligible for this study.
☐Yes ☐No

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Investigator's Signature

- S1605 Registration Worksheet
- S1605 Eligibility Criteria Form

NEW!

Patient Eligibility	
Has the SWOG Registration Worksheet been completed entirely and is the patient eligible according to the current version of protocol Section 5.0?	☐Yes ☐No
I affirm that the eligibility criteria outlined in Section 5.0 of this study have been met. PRIOR TO REGISTRATION	
Registering Investigator	Date

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Increasing Data Quality

With FDA, Not Documented=Not Done

- Increased data monitoring
  - eligibility, treatment, disease assessments or scans
  - CTSU Central Monitoring Portal
- Automatic reports for study-specific information
  - Monitors, Data Coordinators, Statisticians, Sites

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Increasing Data Quality

S1605 : Reminder of Upcoming Protocol-Specified Mandatory Biopsy for Patient ID 703087

seano@crab.org
Sent: Mon 3/26/2018 3:00 AM
To: [redacted]
Cc: seano@crab.org; josephs@crab.org

To Whom it may concern,

Based on our records, patient number 703087 is due for their protocol-specified, mandatory biopsy on 05/09/2018. The allowable window for this procedure is between 05/02/2018 and 05/16/2018.

Please ensure this patient is scheduled for a biopsy within this window. If you are unable to schedule this biopsy or have questions regarding this biopsy requirement, please contact Sean O'Bryan at seano@crab.org. Backup contacts: Melissa Plets (mplets@fredhutch.org), Eddie Mayerson (emayerso@fredhutch.org).

If you are not the person responsible for scheduling this patient for this procedure, please forward this message to the appropriate person.

Thank you for your continued support of S1605!

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Here to help

S1602

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Email: bpcbank@nationwidechildrens.org

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S1605

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THANK YOU

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