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Antibody-Drug Conjugates in Oncology: From Bench to Bedside
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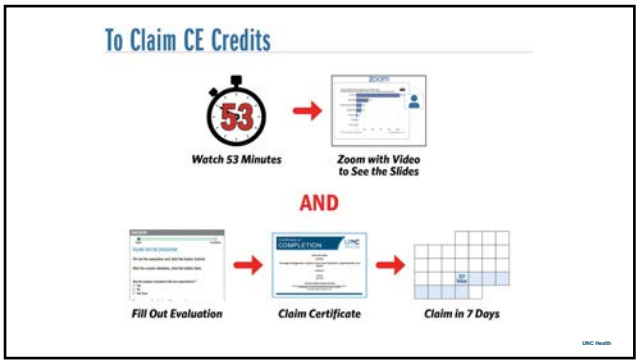
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Our Presenter

Kevin Chen,
PharmD, MS, BCOP, CPP

Kevin Chen, PharmD, MS, BCOP, CPP, is a clinical pharmacist practitioner at University of North Carolina (UNC) Medical Center specializing in the care of patients with thoracic malignancies and sarcoma. He completed his graduate and pharmacy education at the University of Kentucky College of Pharmacy, and subsequently went on to complete his oncology pharmacy residency at UNC Medical Center in 2020. His clinical interests center around precision medicine and dose-optimization of targeted therapies. In his free time, Kevin enjoys traveling, trying new breweries and restaurants, and cycling.

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Our Presenter

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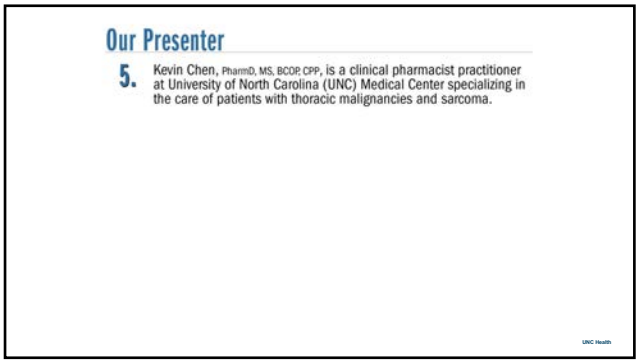
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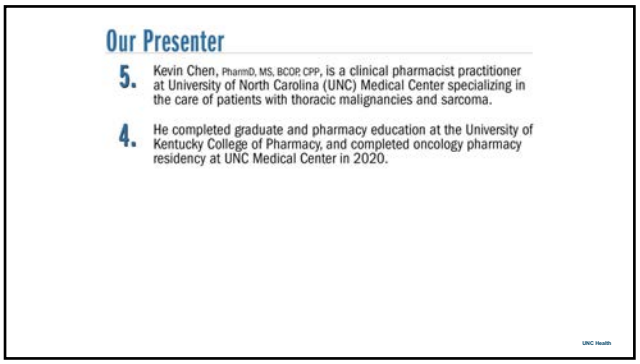
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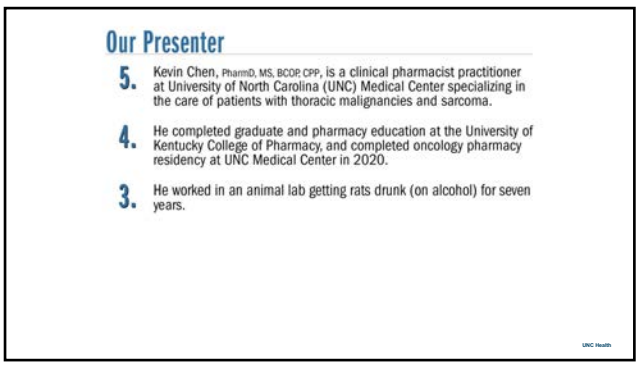
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3. He worked in an animal lab getting rats drunk (on alcohol) for seven years.
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2. He compounded blinatumumab for the first patient treated at University of Kentucky.

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3. He worked in an animal lab getting rats drunk (on alcohol) for seven years.
2. He compounded blinatumumab for the first patient treated at University of Kentucky.
1. He is passionate about improving pharmacy education and research.

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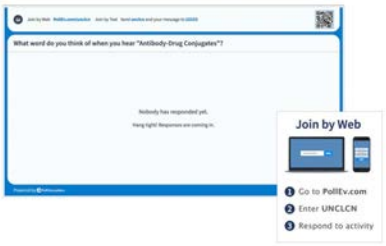
Sample Poll Everywhere Question



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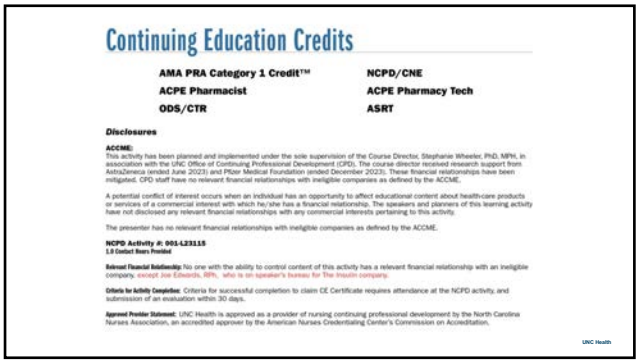
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What word do you think of when you hear "Antibody-Drug Conjugates"?
Nobody has responded yet.
Hang tight! Responses are coming in.

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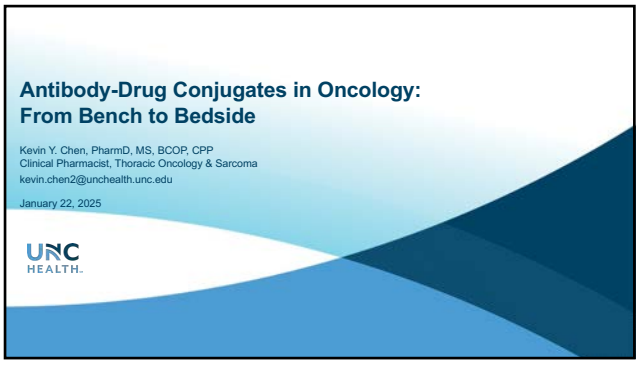
Antibody-Drug Conjugates in Oncology:
From Bench to Bedside
Kevin Y. Chen, PharmD, MS, BCOP, CPP
Clinical Pharmacist, Thoracic Oncology & Sarcoma
kevin.chen2@unchealth.unc.edu
January 22, 2025
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Disclosures

Kevin Y. Chen, has the following financial relationships to disclose:

- Advisory Boards: G1 Therapeutics, Johnson & Johnson, Pfizer, and Bristol Myers Squibb
- Research Funding: Eli Lilly and Company

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Objectives

1. Describe the components of an antibody drug conjugate (ADC) and its mechanism of action
2. Discuss clinical evidence supporting their use as cancer treatment
3. Identify strategies to improve efficacy and tolerability of these novel agents

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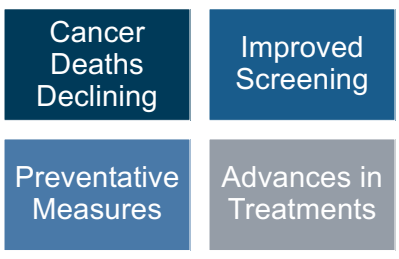
Cancer Outcomes



21 Goddard KAB, et al. JAMA Oncol. 2024 Dec 5:e245381. UNC Health

21

Cancer Treatments

- Cytotoxic Chemotherapy
- Targeted Therapies
- Immunotherapy

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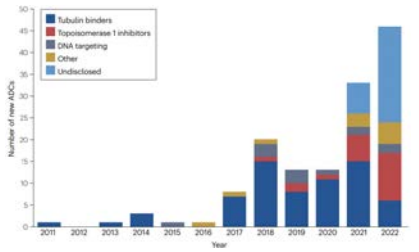
Antibody-Drug Conjugates (ADCs)



23 Dumontet C., et al. *Nat Rev Drug Discov.* 2023;22(8):641-661. UNC Health

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FDA Approved ADCs (1/2025)

Drug	Indication	Approval Date
Gemtuzumab Ozogamicin	Acute Myeloid Leukemia	2000
Brentuximab Vedotin	Hodgkin Lymphoma, T-cell Lymphoma, Anaplastic Large Cell Lymphoma	2011
Trastuzumab Emtansine	Breast Cancer	2013
Inotuzumab Ozogamicin	Acute Lymphoblastic Leukemia	2017
Polatuzumab Vedotin	B-cell Lymphoma	2019
Enfortumab Vedotin	Bladder Cancer	2019
Trastuzumab Deruxtecan	Breast Cancer, Lung Cancer, Gastric Cancer, HER2 Overexpressing Solid Tumors	2019
Sacituzumab Govitecan	Breast Cancer	2020
Tisotumab Vedotin	Cervical Cancer	2021
Loncastuximab Tesirine	B-cell Lymphoma	2021
Mirvetuximab Soravtansine	Ovarian Cancer	2022

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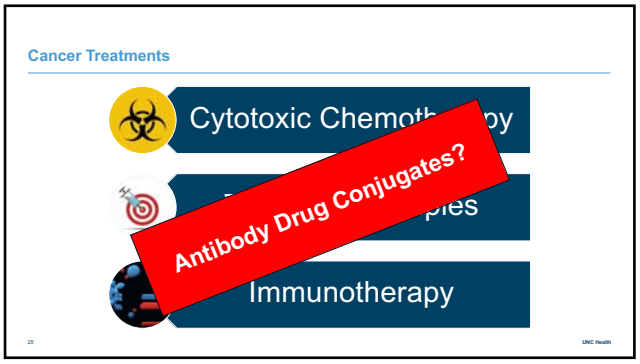
Cancer Treatments
Cytotoxic Chemoth
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Immunotherapy
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Pharmacology
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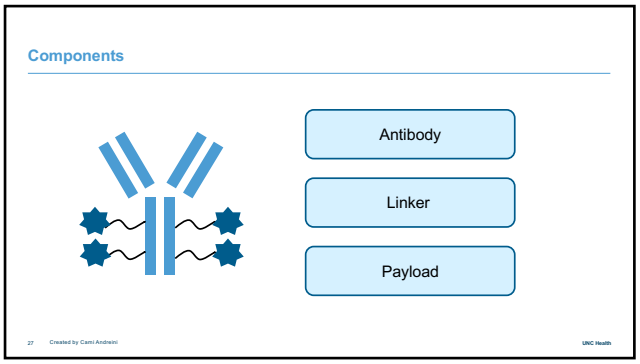
Components
Antibody
Linker
Payload
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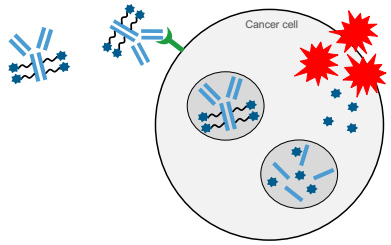
Mechanism of Action



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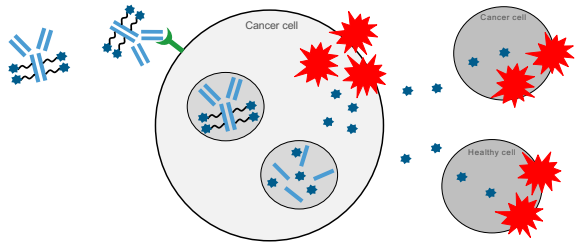
Bystander Effect



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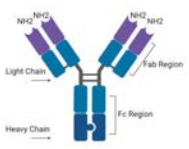
Antibody

- **Binds with high affinity to target antigen**
  - High expression on tumor cells
  - Low expression on healthy cells
  - Cell surface expression
  - High internalization capacity
- **Constant fragment (Fc) considerations**
  - Low immunogenicity
  - Long circulating half-life
- **Can also have additional anti-cancer activity**

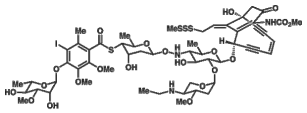


30 Khongorzul P., et al. *Mol Cancer Res.* 2020 Jan;18(1):3-19. UNC Health

30

Payload

- **Exerts cytotoxic effect in cancer cell**
  - Highly potent
  - Stable in circulation & lysosomes
- **Common payloads**
  - DNA damaging agents
  - Microtubule-disrupting agents
  - Topoisomerase I inhibitors
- **May influence bystander effect**



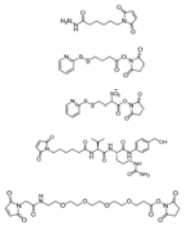
Calicheamicin γ_1

31 Khongorzul P., et al. *Mol Cancer Res.* 2020 Jan;18(1):3-19. UNC Health

31

Linker

- **Conjugates cytotoxic payload to targeting antibody**
  - Stable in circulation
  - Efficient payload release at target site
- **Cleavable vs non-cleavable**
  - Cleavable: acid-labile, proteolysis, glutathione reduction
  - Non-cleavable: requires lysosomal degradation
  - Influences bystander effect
- **Determines drug-to-antibody ratio (DAR)**



32 Khongorzul P., et al. *Mol Cancer Res.* 2020 Jan;18(1):3-19. UNC Health

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ADC Examples

Gemtuzumab Ozogamicin	Brentuximab Vedotin	Trastuzumab Emtansine
• Antibody: CD33 • Payload: calicheamicin (DNA damage) • Linker: hydrolysable (pH-labile)	• Antibody: CD30 • Payload: MMAE (microtubule disruption) • Linker: protease cleavable	• Antibody: HER2 • Payload: DM1 (microtubule inhibitor) • Linker: thioether (non-cleavable)

33 Khongorzul P., et al. *Mol Cancer Res.* 2020 Jan;18(1):3-19. UNC Health

33


Antibody drug conjugates are comprised of the following key components:
Antibody and payload
0%
Antigen, linker, and cytotoxic chemotherapy
0%
Antibody, linker, and payload
0%
Binding domain, linker, and antibody
0%

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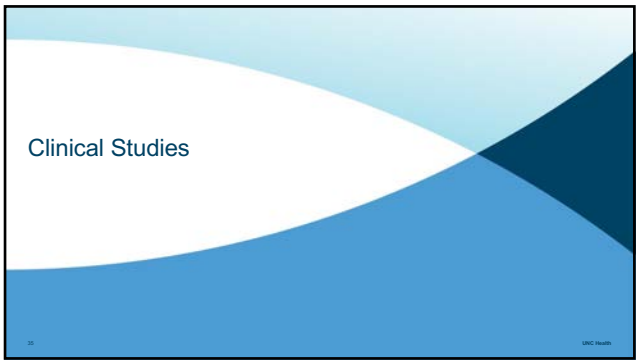
Clinical Studies

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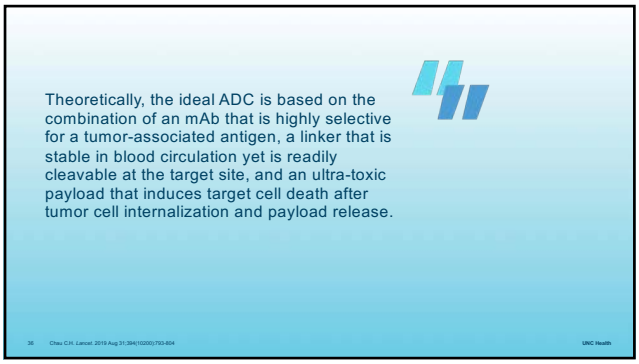
Theoretically, the ideal ADC is based on the combination of an mAb that is highly selective for a tumor-associated antigen, a linker that is stable in blood circulation yet is readily cleavable at the target site, and an ultra-toxic payload that induces target cell death after tumor cell internalization and payload release.

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EMILIA: Trastuzumab Emtansine (T-DM1)

Trial design: phase 3, open-label, randomized trial

Inclusion: HER2 positive (IHC 3+ or FISH+), advanced/metastatic breast cancer, previously treated with trastuzumab and a taxane.

Trastuzumab Emtansine (n = 495) VS **Lapatinib + Capecitabine (n = 496)**

Continue treatment until disease progression or unacceptable toxicity

Efficacy & Safety Outcomes	Lapatinib + Capecitabine	Trastuzumab Emtansine
Overall response rate	30.8%	43.6%
Median PFS, months	6.4	9.6
	0.65 [0.55–0.77]	
Median OS, months	25.1	30.9
	0.68 [0.55–0.85]	
Grade ≥3 toxicities	57.0%	40.8%
All grade toxicities		
- Diarrhea	79.7%	23.3%
- Hand foot syndrome	58.0%	1.2%
- Vomiting	29.3%	19.0%
- Elevated AST	9.4%	22.4%
- Thrombocytopenia	2.5%	28.0%

37 Verma S., et al. *N Engl J Med.* 2012 Nov 8;367(19):1783-91. UNC Health

37

DESTINY-Breast03: Trastuzumab Deruxtecan (T-DXd)

Phase 3, multi-center, open-label, randomized, active controlled trial

Population
- ≥ 18 years
- ECOG PS 0-1
- Unresectable or metastatic breast cancer
- HER2 positive *(IHC 3+ or 2+ & ISH positive)*
- Prior taxane and trastuzumab treatment

RANDOMIZED

- Trastuzumab Deruxtecan (n=261)
- Trastuzumab Emtansine (n=263)

Primary
Progression-free survival

Secondary
Overall survival
Overall response
Safety

38 Cortes J., et al. *N Engl J Med.* 2022 Mar 24;386(12):1143-1154. UNC Health

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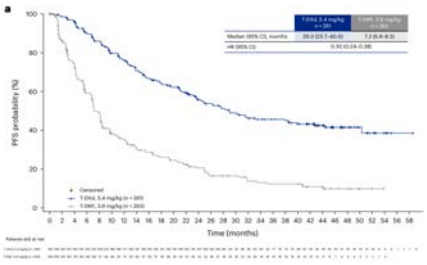
DESTINY-Breast03: Trastuzumab Deruxtecan (T-DXd)

Overall response
79.7% (T-DXd)
34.2% (T-DM1)



39 Cortes J., et al. *N Engl J Med.* 2022 Mar 24;386(12):1143-1154; Cortes J., et al. *Nat Med.* 2024 Aug;30(8):2208-2215. UNC Health

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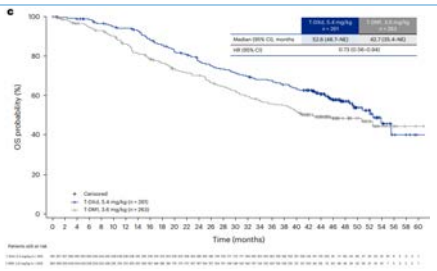
DESTINY-Breast03: Trastuzumab Deruxtecan (T-DXd)



40 Cortes J., et al. *Nat Med.* 2024 Aug;30(8):2208-2215. UNC Health

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T-DXd HER2 Low & Ultralow

DESTINY-Breast04

- HER2 low (IHC 1+ or IHC 2+ & negative ISH)
- T-DXd vs physician choice chemotherapy
- ORR: **52.6% vs 16.3%**
- mPFS: **10.1mo vs 5.4mo** (HR: 0.51; [0.40-0.63])
- mOS: **23.9mo vs 17.5mo** (HR: 0.64; [0.48-0.86])

DESTINY-Breast06

- HER2 ultralow (IHC 0 with membrane staining)
- T-DXd vs physician choice chemotherapy
- ORR: **61.8% vs 26.3%**
- mPFS: **13.2mo vs 8.3mo** (HR: 0.78; [0.40-0.63])

41 Modi S., et al. *N Engl J Med.* 2022 Jul 7;387(1):9-20; Banda A., et al. *N Engl J Med.* 2024 Sep 15;391(22):2110-2122. UNC Health

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T-DXd vs T-DM1

Trastuzumab Deruxtecan (T-DXd)	Trastuzumab Emtansine (T-DM1)
	
Payload: topoisomerase I inhibitor **(DXd)**	Payload: tubulin polymerization inhibitor **(DM1)**
Cleavable linker	**Non-cleavable** linker
High DAR	**Low** DAR

42 Dumontet C. et al. *Nat Rev Drug Discov.* 2023;22(8):641-661. UNC Health

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T-DXd Adverse Effects

	T-DXd		T-DM1	
Toxicity	**Any Grade**	**Grade ≥3**	**Any Grade**	**Grade ≥3**
Neutropenia	42.8%	19.1%	11.1%	3.1%
Anemia	30.4%	5.8%	14.2%	4.2%
Thrombocytopenia	24.9%	7.0%	51.7%	24.9%
Nausea	72.8%	6.6%	27.6%	0.4%
Vomiting	44.0%	1.6%	5.7%	0.4%
Diarrhea	23.7%	0.4%	3.8%	0.4%
Constipation	22.6%	0%	9.6%	0%
Fatigue	44.7%	5.1%	29.5%	0.8%
AST Increase	23.3%	0.8%	37.2%	5.0%
ALT Increase	19.5%	1.6%	27.2%	4.6%
Pneumonitis/ILD	10.5%	0.8%	1.9%	0%

43 Cortes J., et al. *N Engl J Med.* 2022 Mar 24;386(12):1143-1154. UNC Health

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DLL3 ADCs in SCLC

Rovalpituzumab Tesirine (Rova-T)

- Antibody: DLL3
- Payload: pyrrolobenzodiazepine (DNA damage)
- Linker: protease cleavable

TAHOE phase 3 study

- Rova-T vs topotecan
- mOS: 6.3mo vs 8.6mo
- Serous effusions, edema, photosensitivity

SC-002

- Antibody: DLL3
- Payload: pyrrolobenzodiazepine (DNA damage)
- Linker: protease cleavable
  - Designed to be safer than Rova-T

Phase 1 study

- 60% Grade 3/4 toxicities
- Serous effusions, edema, photosensitivity

44 Blackhall F., et al. *J Thorac Oncol.* 2021 Sep;16(9):1547-1558; Morgensztern D., et al. *Lung Cancer.* 2020 Jul;145:126-131. UNC Health

44

ADC Market Withdrawals

Belantamab Mafodotin	Sacituzumab Govitecan	Gemtuzumab Ozogamicin
DREAMM-2	TROPHY-U-01	Study 201/202/203
DREAMM-3	TROPiCS-04	SWOG S0106

45 Lorial S., et al. *Lancet Oncol.* 2020 Feb;21(2):207-221; Dimopoulos M.A., et al. *Lancet Haematol.* 2023 Oct;10(10):e801-e812; Tagawa S.T., et al. *J Clin Oncol.* 2021 Aug 1;39(22):2474-2485; Ghias P., et al. *Ann Oncol.* 2024 Feb;35(2):S1565-S1567; Beltz C., et al. *J Adv Pract Oncol.* 2019 Jan-Feb;10(1):69-82. UNC Health

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TROP2 ADCs in NSCLC

EVOKE-01

- Previously-treated advanced/metastatic NSCLC
- Sacituzumab Govitecan (*n=299*) vs Docetaxel (*n=304*)
- Sacituzumab Govitecan
  - Antibody: Trop-2 monoclonal
  - Payload: topoisomerase 1 inhibitor
  - Linker: hydrolysable (pH-labile)

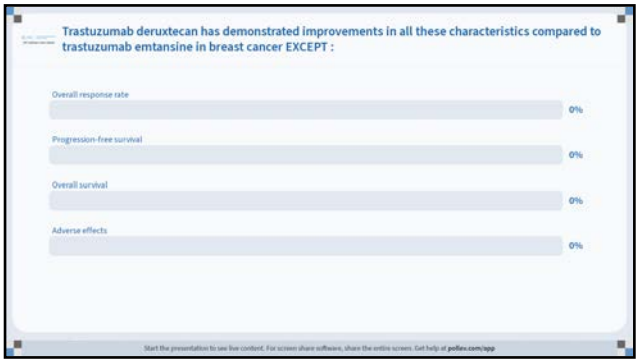
TROPION-Lung01

- Previously-treated advanced/metastatic NSCLC
- Datopotamab Deruxtecan (*n=299*) vs Docetaxel (*n=305*)
- Datopotamab Deruxtecan
  - Antibody: Trop-2 monoclonal
  - Payload: topoisomerase 1 inhibitor
  - Linker: protease cleavable

Overall Survival by Histology		
	EVOKE-01	TROPION-Lung01
Non-squamous	HR = 0.87	HR = 0.84
Squamous	HR = 0.83	HR = 1.32

46 Ahn M.J., et al. J Clin Oncol. 2024 Sep 9:JCO2401544; Paz-Ares L.G., et al. J Clin Oncol. 2024 Aug 20;42(24):2860-2872. UNC Health

46



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ADC Optimization

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Optimization Opportunities

Toxicity | Biomarkers | Resistance

Targeting | Payloads

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ADC Toxicities

Payload →

Payload	Common Toxicities
Topoisomerase I Inhibitors	Diarrhea, neutropenia
DM1	Thrombocytopenia, hepatotoxicity
DM4	Ocular toxicity
MMAE	Peripheral neuropathy, myelotoxicity
MMAF	Ocular toxicity
Calicheamicins	Neutropenia

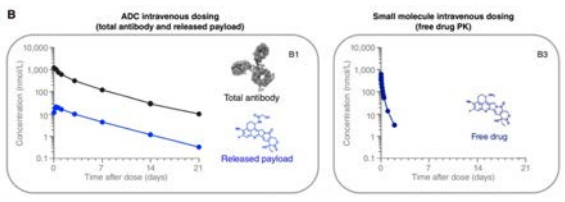
Antibody →

Target Antigen	Common Toxicities
HER2	Cardiotoxicity
Trop2	Rash, mucositis
Nectin-4	Rash, dysgeusia
Tissue factor	Bleeding

50 Tarantino P., et al. *Nat Rev Clin Oncol.* 2023;20(8):558-576. UNC Health

50

ADC Kinetics



51 Colombo R., et al. *Cancer Discov.* 2024 Nov 1;14(11):2089-2108. UNC Health

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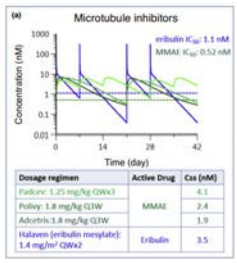
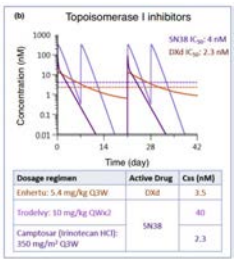
ADC Systemic Exposure



Dosage regimen	Active Drug	Css (nM)
Padcev: 1.25 mg/kg Q3Wx3	MMAE	4.1
Polivy: 1.8 mg/kg Q3W		2.4
Adcetris:1.8 mg/kg Q3W		1.9
Halaven (eribulin mesylate): 1.4 mg/m² Q3Wx2	Eribulin	3.5



Dosage regimen	Active Drug	Css (nM)
Enhertu: 5.4 mg/kg Q3W	DXd	3.5
Trodelvy: 10 mg/kg QWx2	SN38	40
Camptosar (irinotecan HCl): 350 mg/m² Q3W		2.3

52 Tarcsa E., et al. *Drug Discov Today Technol.* 2020 Dec:37:13-22 UNC Health

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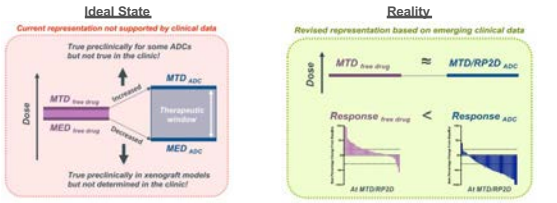
ADC Therapeutic Window



53 Conroy R. & Rich J.R. *Cancer Cell.* 2022 Nov 14;40(11):1255-1263. UNC Health

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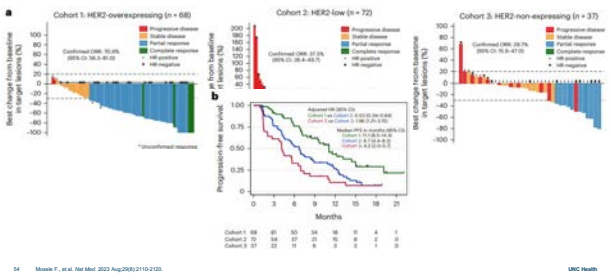
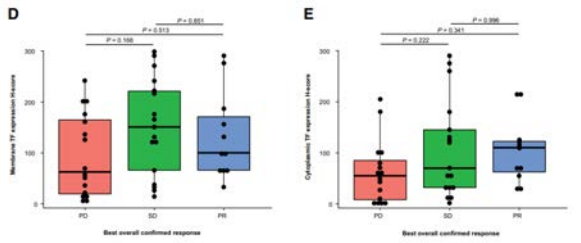
Biomarkers: T-DXd



54 Modi S., et al. *Nat Med.* 2023 Aug;29(8):2110-2120. UNC Health

54

Biomarkers: Tisotumab Vedotin



55 Hong D.S., et al. *Clin Cancer Res.* 2020 Mar 15;26(6):1220-1228. UNC Health

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ADC Biomarkers

56 Ascione L., et al. *Am Soc Clin Oncol Educ Book.* 2024 Jun 1;44(3):e431766. UNC Health

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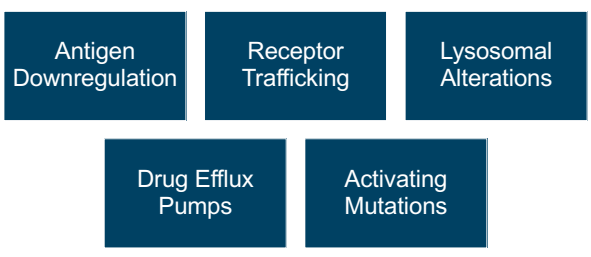
Mechanisms of Resistance



57 Garcia-Alonso S., et al. *Cancer Res.* 2018 May 1;78(9):2159-2165. UNC Health

57

Future Directions

Linker
- Modify hydrophobicity
- Dual-payloads

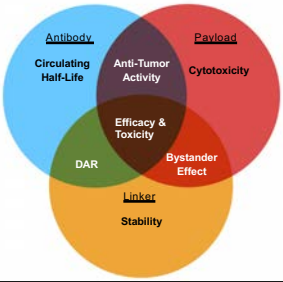
Antibody
- Bi-specific or biparatropic binding
- Extracellular targets

Payload
- Immune-stimulating agents
- Radioligands

58 Drago Z.D., et al. *Nat Rev Clin Oncol.* 2021 Jun;18(6):327-344. UNC Health

58

ADC Complexity



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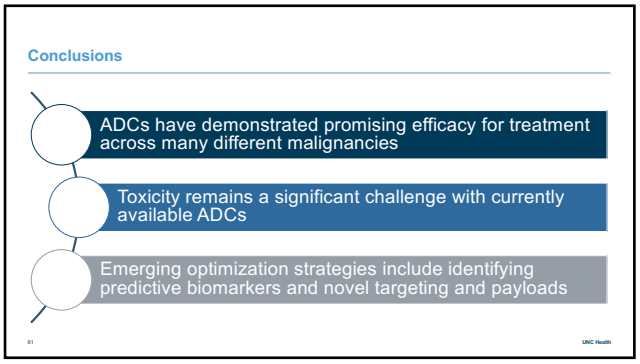
Conclusions
ADCs have demonstrated promising efficacy for treatment across many different malignancies
Toxicity remains a significant challenge with currently available ADCs
Emerging optimization strategies include identifying predictive biomarkers and novel targeting and payloads
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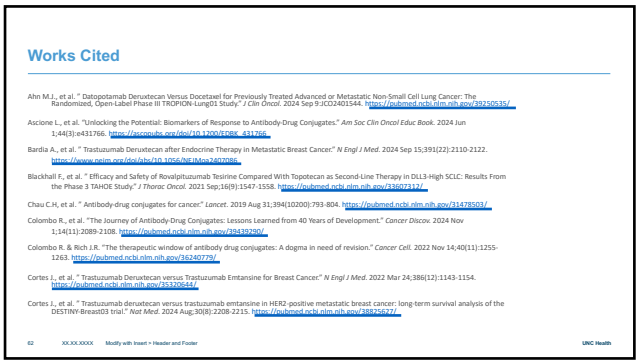
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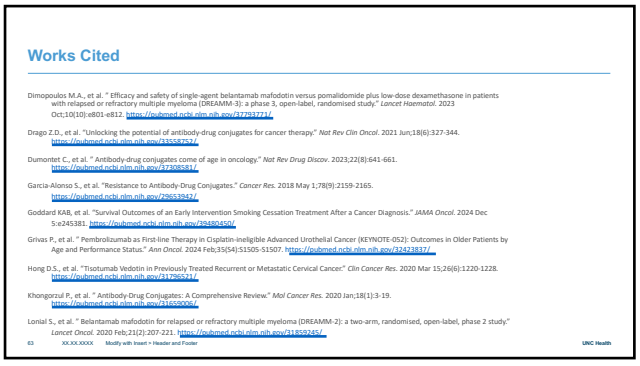
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Antibody-Drug Conjugates in Oncology: From Bench to Bedside

Kevin Y. Chen, PharmD, MS, BCOP, CPP
Clinical Pharmacist, Thoracic Oncology & Sarcoma

January 22, 2025

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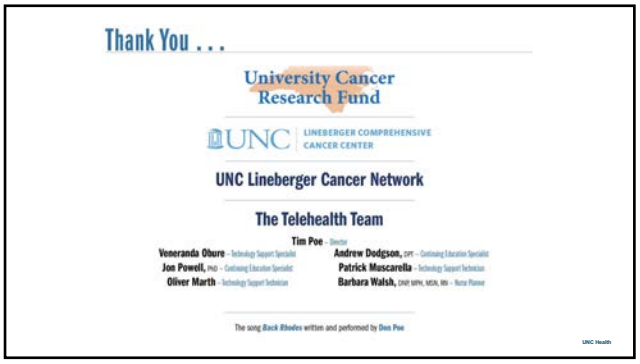
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