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# Phase II Study of Dasatinib in Advanced Sarcomas SARC009

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GIST PI: Jon Trent

Registration and eCRF: CRAB, Seattle

Drug supply and support: Bristol-Myers Squibb

SARC: May 29, 2009

# SARC009: study objectives

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## Primary

- Evaluate clinical benefit rate = Choi response or lack of progression for  $\geq 6$  months

## Secondary

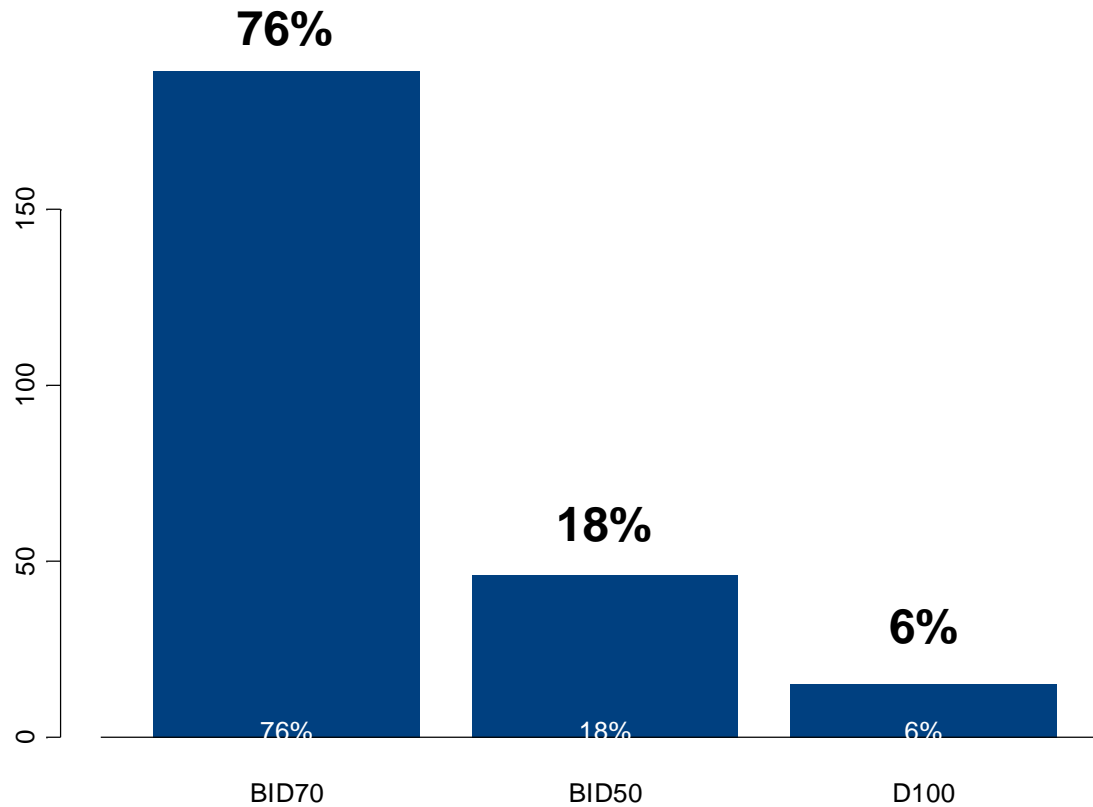
- Evaluate 2 and 5 year survival rates
- Assess clinical and laboratory toxicities
- Collect tissue and blood for correlative studies

# Dose Adjustment

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- Dasatinib dosing scheme
  - 100 mg bid “original” starting dose
  - 70 mg bid “revised” starting dose
  - 50 mg bid, level -1
  - 100 mg once daily, level -2

# Dasatinib dose



# SARC009: Imaging

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- Imaging every 8 weeks +/- 1 week, same method as baseline
- Size = sum of greatest dimension of targets
- Density (CT only) = sum of average density of targets

# Choi criteria

- CR = complete disappearance, no new lesions
- $PR_{\text{size}} = >10\%$  reduction in size
- $PR_{\text{density}} = >15\%$  decrease in density
- Stable = neither CR, PR or PD
- PD =  $>10\%$  increase in size but not  $>15\%$  decrease in density, or new lesions  $>1\text{cm}$ , or unequivocal progression of non-target lesions, or clinical deterioration from sarcoma

# SARC 009: “Aggressive” sub-types enrollment

- MFH – 48 **closed**
- Osteosarcoma – 42 **open**
- Leiomyosarcoma – 49 **closed**
- Liposarcoma – 11 **closed**
- Ewing’s family – 15 **open**
- MPNST – 10 pending eval
- Rhabdomyosarcoma – 9 pending eval

N = min 9 to max 48 per stratum

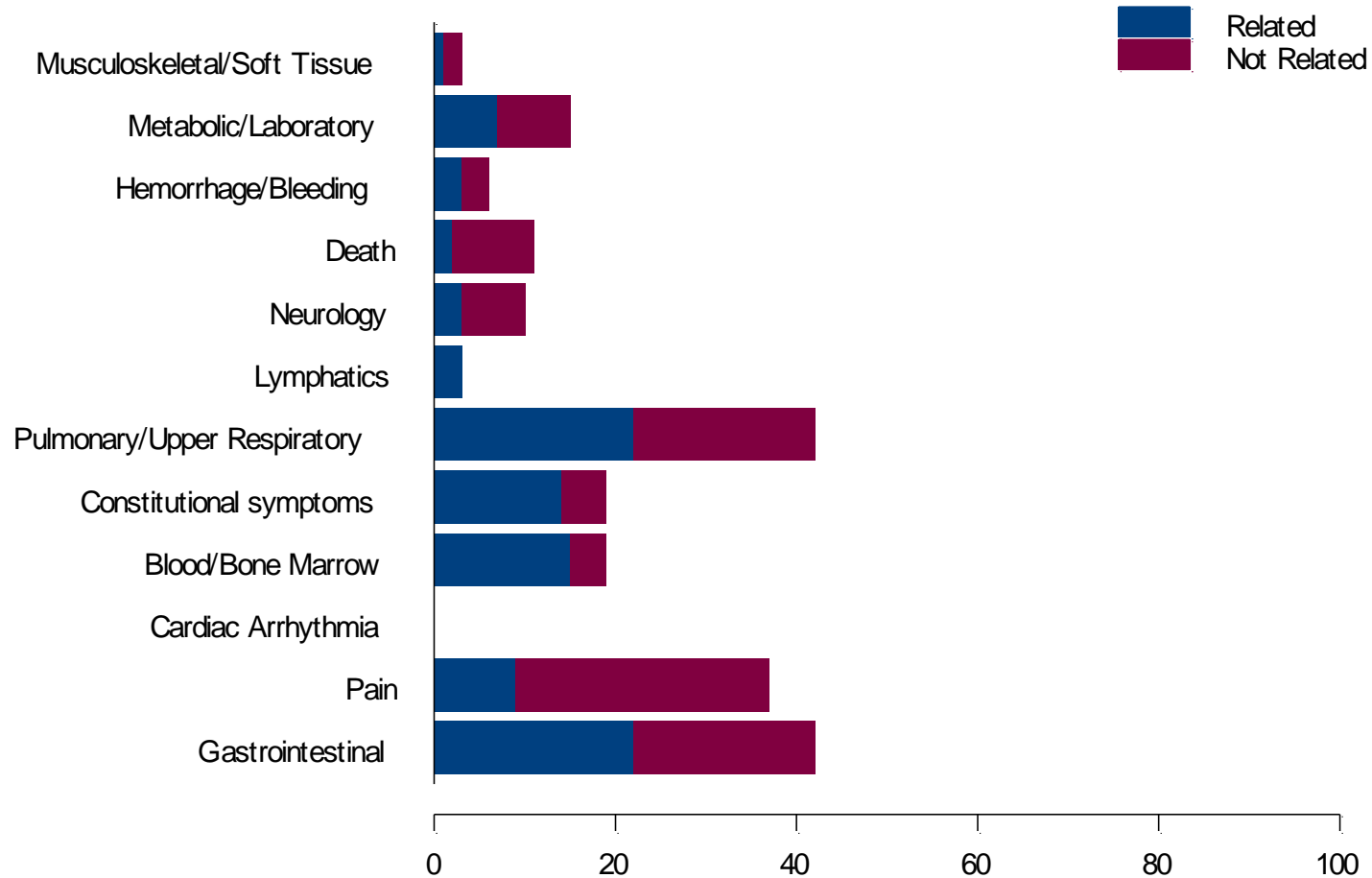
# SARC009: “Indolent” stratum enrollment

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- ASPS – 8
- Chordoma – 15
- Conventional chondrosarcoma – 24
- Epithelioid sarcoma – 5
- GCT – 0
- Hemangiopericytoma – 19

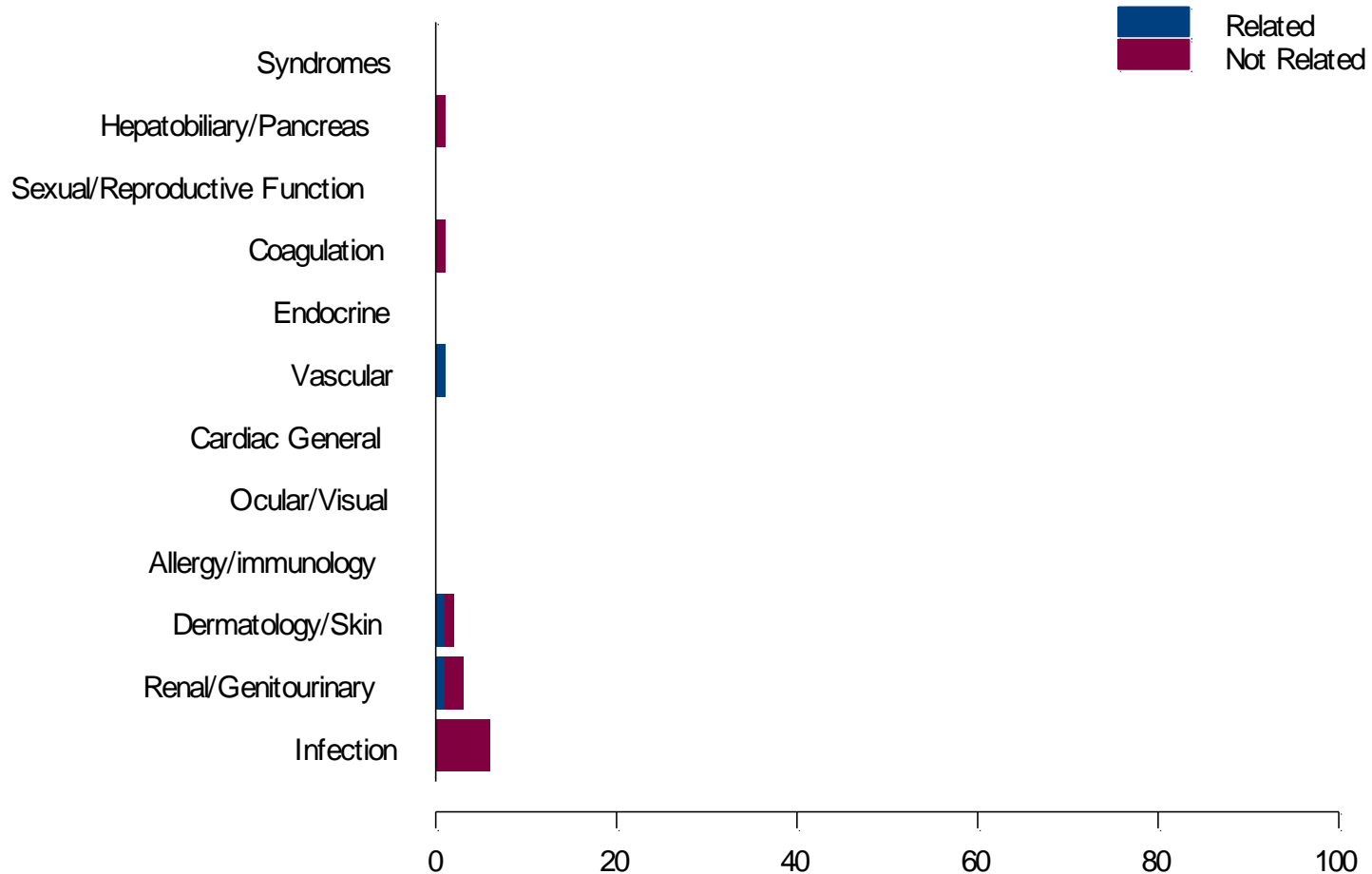
Current N = 71 (maximum 116)

# Grade $\geq 3$ AE

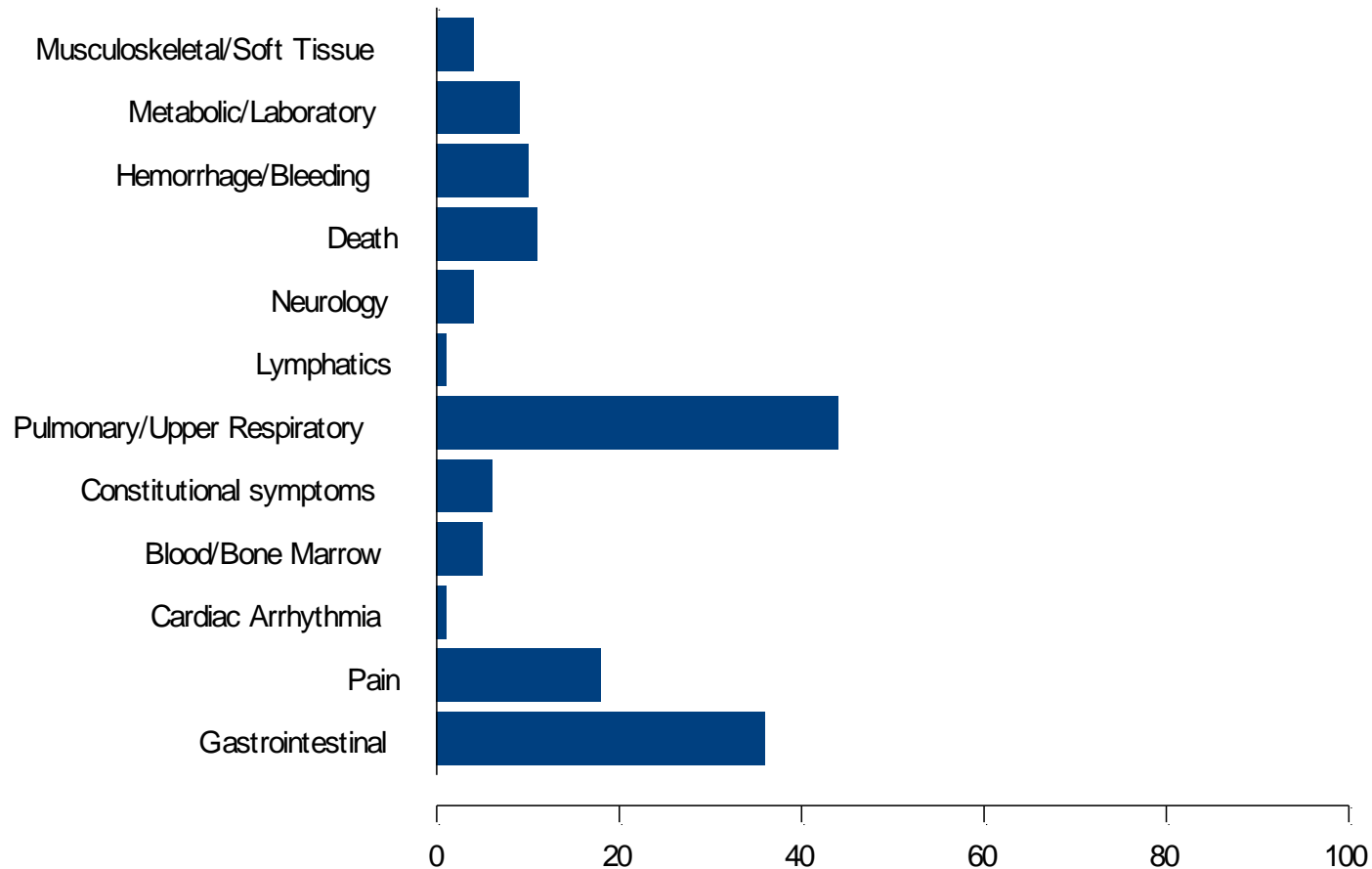


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# Grade $\geq 3$ AE

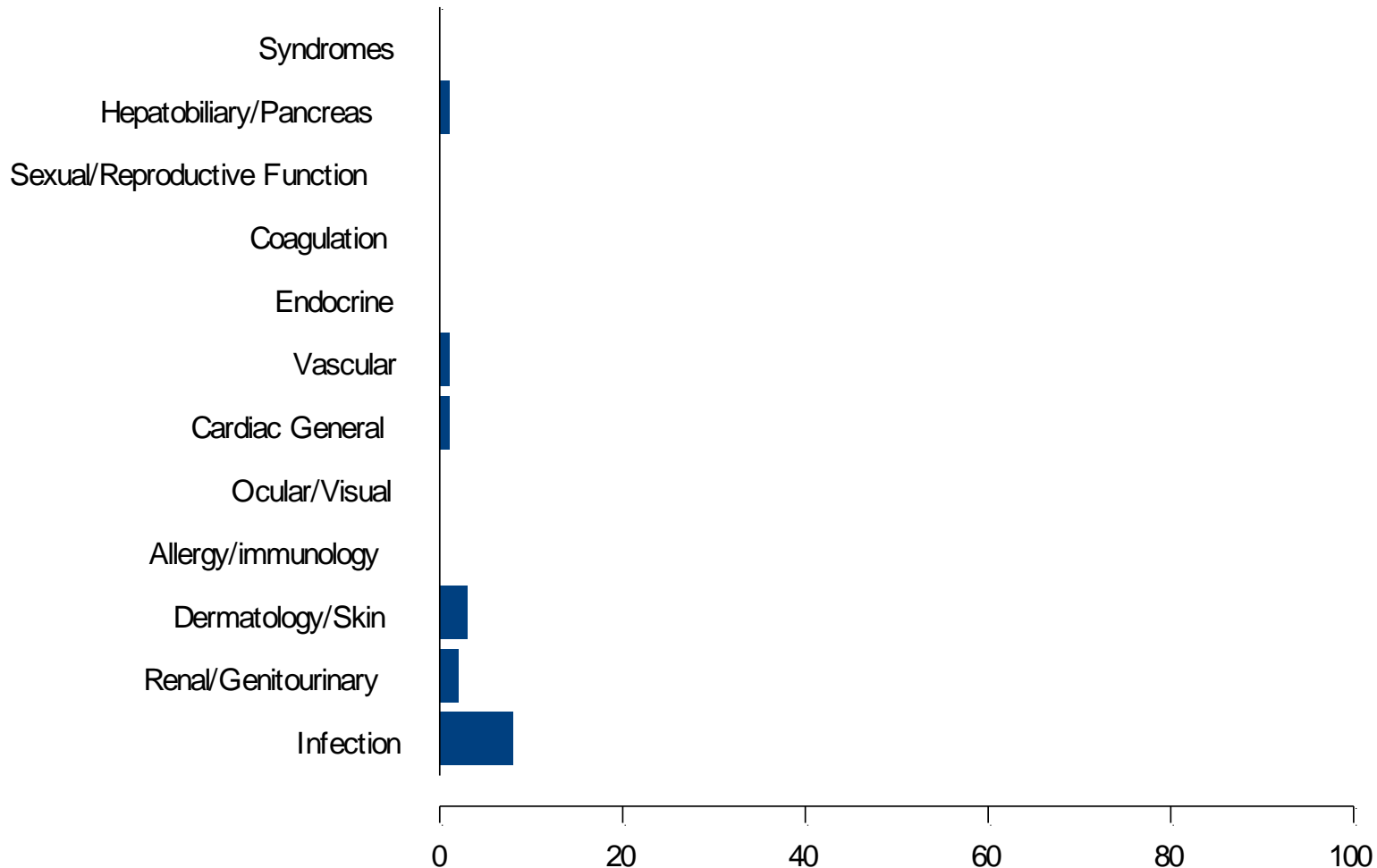


# Dasatinib-related SAEs



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# SARC009: statistical design

- Bayesian / dynamic analysis
- Start analysis after enrollment 9-10 per subtype
- “aggressive” subtypes -  $\geq 25\%$  clinical benefit rate
- “indolent” group – 6 month PFS
  - $> 50\%$  = promising
  - $< 30\%$  = inactive
- GIST - 6 month PFS
  - $> 30\%$  = promising
  - $< 10\%$  = inactive

# SARC009: summary

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- Completing accrual in “aggressive “ sarcomas
- Preliminary results show activity in “MFH” and osteosarcoma
- “indolent” group continues accrual
- AEs: hematologic, pulmonary, GI, constitutional, pain
- Continued follow-up for survival is needed
- Thanks to SARC staff for excellent support!